12-19-03

1614

PATENT
Attorney Docket No. 03136646

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
)
R. Eric MONTGOMERY) Group Art Unit: 1614
)
Application No. 10/039,935) Examiner: Duane JONES
)
Filed: November 1, 2001)
)
For: TOOTH BLEACHING) COMPOSITIONS)

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Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR PROPRIETARY DOCUMENTS

Dear Sir:

Enclosed herewith are the following for the above-captioned application:

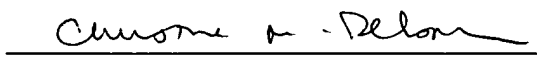
1. September 17, 2003 Transmittal Letter for Proprietary Documents;
2. Response to Office Action;
3. Pending or Issued Claims from 26 applications and patents in the name of R. Eric Montgomery;
4. Specification and patent filing for U.S. Patent No. 10/434,597, filed May 9, 2003; and
5. Return Post Card.

The materials in the attached sealed envelope, including a Response to Office Action of March 18, 2003, are considered proprietary, and are being submitted for consideration under MPEP § 724.

These materials are being resubmitted. They were originally mailed on September 17, 2003 but never made it to the patent file as indicated by Examiner Krass in a December 9, 2003 telephone interview.

The Commissioner is hereby authorized to charge any additional filing fees required under Rule 1.17 concerning this transaction, or to credit any overpayment to Deposit Account 13-0019.

Respectfully submitted,



Christine M. Rebman
Reg. No. 50,546

Date: December 18, 2003

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PROPRIETARY

PATENT
Attorney Docket No. 03136646

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

R. Eric MONTGOMERY

Application No. 10/039,935

Filed: November 1, 2001

For: TOOTH BLEACHING COMPOSITIONS

Group Art Unit: 1614

Examiner: Shep K. ROSE

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Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR PROPRIETARY DOCUMENTS

Dear Sir:

The materials in the attached sealed envelope, including a Response to Office Action of March 18, 2003, are considered proprietary, and are being submitted for consideration under MPEP § 724.

Respectfully submitted,

Christine M. Rebman
Reg. No. 50,546

Date: September 17, 2003

MAYER, BROWN, ROWE & MAW LLP
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Chicago, Illinois 60690-2828
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PROPRIETARY

PATENT
ATTORNEY DOCKET NO. 03136646

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

R. Eric Montgomery

Application No.: 10/039,935

Filed: November 1, 2001

Title: TOOTH BLEACHING COMPOSITIONS

Examiner: Shep K. Rose

Art Unit: 1614

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

This is in response to the Office Action dated March 18, 2003. The original period of response to the Office Action is a shortened statutory period of one (1) month from the mailing date of the Office Action. Extensions of time are available under 37 C.F.R. §1.36(a) for up to six months from March 18, 2003. This response is timely if filed on or before September 18, 2003, in accordance with 37 CFR §1.10. If there are any additional fees due in connection with the filing of this response, please charge these additional fees (or credit any overpayment) associated with this communication to our Deposit Account No. 13-0019. Applicant respectfully requests reconsideration and allowance of the pending claims.

REMARKS

I. Status of the Application

Claims 42-70 are pending in the application. Applicant respectfully requests entry and consideration of the remarks, which are intended to place this case in condition for allowance. This response and the attached exhibits have been marked "Proprietary" and are being submitted, pursuant to M.P.E.P. § 724.02, in a sealed, clearly labeled, envelope marked ""PROPRIETARY MATERIAL NOT OPEN TO PUBLIC. TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED U.S. PATENT AND TRADEMARK OFFICE EMPLOYEE." Applicant submits under separate cover a supplemental Information Disclosure Statement ("IDS") complying with the Examiner's request.

The Examiner asserts that the reply filed by Applicant on February 10, 2003 was not fully responsive. The Examiner requests copies of all claims in all copending applications and patents "if they claim any apparatus, device, kits, or other means, that would be material, relevant and important to the issues of patentability, for the purpose of investigation of the issue of obviousness-type double patenting of dual ("first tube" and "second tube") tooth bleaching equipment as in newly presented claims 42-70."

In response, Applicant's attorney provides herein a list of Montgomery patents and applications of which Applicants' attorney are currently aware that may be responsive to the Examiner's request. It is possible that other cases may be handled by other attorneys, but at this time Applicant's attorney believes that it is currently responsible for all of Montgomery's human oral care patent prosecution. Copies of these references will be provided under separate cover in a supplemental IDS to the extent that they have issued or published.

09/483,526*	5,738,843	6,331,292
09/651,170**	5,816,802	6,343,933
09/840,844	5,908,614	6,475,469
10/039,935	5,922,307	6,479,037
10/050,196	5,944,528	6,488,914
10/056,296	6,162,055	6,514,543
10/219,965***	6,221,341	6,536,628
10/434,597	6,281,265	6,576,227
10/456,205****	6,312,670	
WO 99/40870	6,322,773	

*Applicant's attorney submitted in the supplemental IDS PCT Publication No. WO 01/51005, which includes the same specification as U.S. Application Serial No. 09/483,526 (the '526 application is not yet published in the U.S.).

**U.S. Application No. 09/651,170 is a continuation of issued U.S. Patent No. 6,162,055, which is provided in the IDS; therefore, Applicant's attorney is not including a copy of this application since the specification is the same. The claims will be provided, however, as indicated below.

***U.S. Application Serial No. 10/219,965 is being handled by another law firm, but Applicant's attorney is including a copy of the published application for the Examiner's convenience.

****U.S. Application No. 10/456,205 is a continuation of issued U.S. Patent No. 5,908,614, which is provided in the IDS; therefore, Applicant's attorney is not including a copy of this application since the specification is the same. The claims will be provided, however, as indicated below.

Copies of currently pending claims and issued claims corresponding to the list are also provided herewith, with the exception of WO 99/40870, which is a PCT application, and U.S. Application Serial No. 10/219,965, which is being handled by another law firm. The claims for

applications that have not yet published or issued are marked "Proprietary" to prevent public access prior to publication or issuance of those applications.

Applicant believes that the submitted information is complete but reserves the right to supplement upon further discovery of such information.

The arguments made herein should in no way be construed as dedicating any unclaimed or amended subject matter or equivalents to the public, and were done solely to expedite prosecution. Applicant reserves the right to pursue any cancelled or amended subject matter in this or related applications.

II. CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicant's attorney would expedite prosecution of the above-identified application, the Examiner is requested to call the undersigned at 312-701-7174.

Respectfully submitted,

Dated: Sept 17, 2003

Christine M. Rebman, Reg. No. 50,546
MAYER, BROWN, ROWE & MAW LLP
190 South LaSalle Street
Chicago, IL 60603
312-782-0600

PATENT
Docket No. 03025837

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

PILARO et al.

Application No. 09/483,526

Filed: January 14, 2000

For: TOOTH WHITENING AND IMAGE ENHANCEMENT CENTER METHOD

Group Art Unit: 3732

Examiner: J. WILSON

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Timothy Hubalik
(typed or printed name of person mailing paper or fee)

(signature of person mailing paper or fee)

AMENDMENT AND RESPONSE TO AUGUST 15, 2002, FINAL OFFICE ACTION

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Amendment is submitted in response to the final Office Action mailed August 15, 2002. This response is accompanied by a Petition to Revive Unintentionally Abandoned Application under 35 C.F.R. § 1.137. Upon granting of the Petition, this response is timely filed.

If there are any additional fees due in connection with the filing of this response, please charge these additional fees (or credit any overpayment) associated with this communication to our Deposit Account No. 13-0019. Applicant respectfully requests amendment of the patent application and reconsideration and allowance of the pending claims.

IN THE CLAIMS

Please add new claims 59-63.

Please substitute claims 1, 40-41, 48-49 and 54 with the corresponding amended claims as follows:

1. (Amended) A method of providing tooth whitening services to a plurality of clients by one dental professional, which comprises:

(a) providing a tooth whitening module comprising at least two workstations, each workstation in the module being operated by the dental professional;

(b) assigning each client to a workstation of the module; and

(c) having the dental professional administer tooth whitening services to each client in each workstation of the module,

wherein at least a portion of the tooth whitening procedure is provided to each client simultaneously.

40. (Amended) A method of administering tooth whitening services, comprising the steps of:

(a) applying a whitening gel to all cosmetically visible teeth of a client; and

(b) applying light to all of said teeth of said client simultaneously for a fixed period of time, and

(c) repeating steps (a) and (b) two to five times.

41. (Amended) The method of claim 40, wherein steps (a) and (b) are repeated from about two to about five times, and wherein steps (a) – (c) are completed in less than about two hours.

48. (Amended) A method according to claim 40, wherein the whitening gel comprises from about 1% to about 35% hydrogen peroxide.

49. (Amended) A method according to claim 40, further comprising a step of comparing the shade of teeth to a desired shade on a shade guide.

54. (Amended) The method of claim 53, wherein the means of receiving contacts initiated by potential clients and informing said potential clients of locations where tooth whitening services can be obtained through a telephonic connection, a web site, email or written correspondence.

59. (New) The method of claim 40, wherein the whitening gel comprises from about 5% to about 35% hydrogen peroxide.

60. (New) The method of claim 40, wherein the whitening gel comprises from about 3% to about 20% hydrogen peroxide.

61. (New) The method of claim 40, wherein the whitening gel comprises from about 6% to about 15% hydrogen peroxide.

62. (New) The method of claim 40, wherein the whitening gel comprises an oxidizing compound.

63. (New) The method of claim 62, wherein the oxidizing compound is selected from the group consisting of hydrogen peroxide, carbamide peroxide, calcium peroxide, sodium perborate, potassium persulfate, peracetic acid, metal peroxides, alkali metal percarbonates, and alkali metal perborates.

64. (New) The method of claim 63, wherein the oxidizing compound comprises hydrogen peroxide.

65. (New) The method of claim 63, wherein the oxidizing compound comprises hydrogen peroxide and carbamide peroxide.

66. (New) The method of claim 62, wherein the oxidizing compound comprises a peroxyacid compound.

67. (New) The method of claim 66, wherein the peroxyacid compound is selected from the group consisting of peroxyacetic acid and a peroxyacid precursor compound.

68. (New) The method of claim 67, wherein the peroxyacid precursor compound is selected from the group consisting of glyceryl triacetate, acetylated amino acids, acetylsalicylic acid, and N,N,N',N'-tetraacetyl ethylenediamine, vinyl acetate polymers and copolymers, acetylcholine, and other biologically acceptable acetylated compounds.

69. (New) The method of claim 40, wherein the whitening gel comprises a photosensitizing agent.

70. (New) The method of claim 69, wherein the photosensitizing agent is selected from the group consisting of semiconductor particles, benzophenone derivatives, benzotriazole derivatives, diketones, metal-ligand complexes, and phthalocyanin-metal complexes.

71. (New) The method of claim 70, wherein the photosensitizing agent comprises a semiconductor particles are selected from the group consisting of titanium dioxide and zinc oxide.

72. (New) The method of claim 70, wherein the photosensitizing agent comprises a diketones selected from the group consisting of camphorquinone and benzil.

73. (New) The method of claim 70, wherein the photosensitizing agent comprises a metal-ligand complexes selected from the group consisting of ferric potassium oxalate, manganese gluconate, ethylenediamine tetraacetic acid, diethylenetriamine pentaacetic acid, nitrilotriacetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra(methylenephosphonic acid), diethylenetriamine penta(methylenephosphonic acid), sorbitol, xylitol, mannitol, maltitol, and lactitol.

74. (New) The method of claim 40, wherein the whitening gel comprises an oxidizing compound and a photosensitizing agent.

75. (New) The method of claim 74, wherein the oxidizing compound comprises hydrogen peroxide and the photosensitizing agent comprises ethylenediamine tetraacetic acid.

76. (New) The method of claim 40, further comprising the step of treating the teeth with a desensitizing composition after steps (a) and (b) are repeated two to five times.

77. (New) The method of claim 76, wherein the desensitizing composition comprises at least one of potassium nitrate and fluoride.

78. (New) The method of claim 76, wherein the desensitizing composition comprises from about 3% to about 6% potassium nitrate by weight of the composition.

79. (New) A method of providing tooth whitening services to a plurality of clients by one dental professional, which comprises:

(a) providing a tooth whitening module comprising at least two workstations, each workstation in the module being operated by the dental professional;

(b) assigning each client to a workstation of the module; and

(c) having the dental professional administer tooth whitening services to each client in each workstation of the module,

wherein the tooth whitening services comprises the steps of:

(i) applying a whitening gel to all of the cosmetically visible teeth of the client;

(ii) applying light to all of the teeth simultaneously for a fixed period of time; and

(iii) repeating steps (i) and (ii) two to five times.

80. (New) A method of providing tooth whitening services to a plurality of clients by one dental professional, which comprises:

(a) providing a tooth whitening module comprising at least two workstations, each workstation in the module being operated by the dental professional;

(b) assigning each client to a workstation of the module; and

(c) having the dental professional administer tooth whitening services to each client in each workstation of the module,

wherein the tooth whitening services comprises the steps of:

(i) applying a whitening gel to all of the cosmetically visible teeth of the client;

(ii) applying light to all of the teeth simultaneously for a fixed period of time of about 15 to about 30 minutes; and

(iii) repeating steps (i) and (ii) two to five times.

81. (New) A method of providing tooth whitening services to a plurality of clients by one dental professional, which comprises:

(a) providing a tooth whitening module comprising at least two workstations, each workstation in the module being operated by the dental professional;

(b) assigning each client to a workstation of the module; and

(c) having the dental professional administer tooth whitening services to each client in each workstation of the module,

wherein the tooth whitening services comprises the steps of:

(i) applying a whitening gel to all of the cosmetically visible teeth of the client;

(ii) applying light to all of the teeth simultaneously for a fixed period of time of about 20 minutes; and

(iii) repeating steps (i) and (ii) three times.

---

82. (New) A method of administering tooth whitening services, comprising the steps of:

(a) applying a whitening gel to all cosmetically visible teeth of a client; and

(b) applying light to all of the teeth simultaneously for a fixed period of time of about 15 to about 30 minutes, and

(c) repeating steps (a) and (b) two to five times.

83. (New) A method of administering tooth whitening services, comprising the steps of:

(a) applying a whitening gel to all cosmetically visible teeth of a client; and

(b) applying light to all of the teeth simultaneously for a fixed period of time of about 20 minutes, and

(c) repeating steps (a) and (b) three times.

Pending Claims in U.S. Application Ser. No. 09/651,170

Claims 6, 14, and 25-43 are pending.

Claims 1-5 (Cancelled)

Claim 6 (Previously amended) A tooth whitening composition for use in light-activated tooth whitening, comprising:

a transparent first component comprising a carrier compound; and

a transparent second component comprising an oxidizing compound which when applied to a stained tooth and exposed to actinic light is activated to facilitate tooth whitening;

wherein said second component comprises a peroxyacid precursor selected from the group consisting of glyceryl triacetate, acetylated amino acids, acetylsalicylic acid and tetraacetylethyldiamine.

Claims 7-13 (Cancelled)

Claim 14 (Previously amended) A tooth whitening composition for use in light-activated tooth whitening, comprising:

a transparent first component comprising a carrier compound; and

a transparent second component comprising an oxidizing compound which when applied to a stained tooth and exposed to actinic light is activated to facilitate tooth whitening;

a third component being a photoactivating agent comprising a semiconductor particles, which when exposed to actinic light enhances the activation of said second component to facilitate tooth whitening; wherein said semiconductor particles are nanometer sized oxides of titanium or zinc.

Claims 15-24 (Cancelled)

Claim 25 (Previously amended) A two-part tooth whitening system, comprising:

a first part comprising a metal ion chelator that is capable of activating tooth whitening when in contact with indigenous metal ions in the mouth, said first part also comprising a pH-adjusting agent; and,

a second part comprising hydrogen peroxide.

Claim 26 (Previously added) A two-part tooth whitening system according to claim 25, wherein the metal ion chelator is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DETPA), nitrilotriacetic acid (NTA), 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra(methylenephosphonic acid), and diethylenetriamine penta(methylenephosphonic acid).

Claim 27 (Previously added) A two-part tooth whitening system according to claim 25, wherein the metal ion chelator is a non-carboxylated polyhydroxy compound.

Claim 28 (Previously added) A two-part tooth whitening system according to claim 27, wherein the non-carboxylated polyhydroxy compound is selected from the group consisting of sorbitol, xylitol, mannitol, maltitol, and lactitol.

Claim 29 (Previously added) A two-part tooth whitening system according to claim 25, wherein the hydrogen peroxide is present at a concentration between about 3 percent by weight to about 15 percent by weight.

Claim 30 (Previously added) A two-part tooth whitening system according to claim 25, wherein the first part is aqueous and alkaline.

Claim 31 (Previously added) A two-part tooth whitening system according to claim 25, wherein the first part further comprises ions of one or more transition metals.

Claim 32 (Previously added) A two-part tooth whitening system, comprising:

a first part comprising a metal ion chelator which, in the absence of transition metal ions, is transparent to light of wavelengths from about 350 nm to about 700 nm, but in the presence of a metal ion, becomes an activator capable of absorbing light of wavelengths from about 350 nm to about 700 nm, and wherein the first part also comprises a pH-adjusting agent; and,

a second part comprising hydrogen peroxide.

Claim 33 (Previously added) A two-part tooth whitening system according to claim 32, wherein the metal ion chelator is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DETPA), nitrilotriacetic acid (NTA), 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra(methylenephosphonice acid), and diethylenetriamine penta(methylenephosphonic acid).

Claim 34 (Previously added) A two-part tooth whitening system according to claim 32, wherein the metal ion chelator is a noncarboxylated polyhydroxy compound.

Claim 35 (Previously added) A two-part tooth whitening system according to claim 34, wherein the noncarboxylated polyhydroxy compound is selected from the group consisting of sorbitol, xylitol, mannitol, maltitol, and lactitol.

Claim 36 (Previously added) A two-part tooth whitening system according to claim 32, wherein the hydrogen peroxide is present at a concentration between about 3 percent by weight to about 15 percent by weight.

Claim 37 (Previously added) A two-part whitening system according to claim 32, wherein the first part is aqueous and alkaline.

Claim 38 (Previously added) A two-part whitening system according to claim 32, wherein the first part further comprises ions of one or more transition metals.

Claim 39 (Previously added) A two part tooth whitening system, comprising:

an alkaline first part comprising a pH-adjusting agent and a metal ion chelator that, when bound to a metal ion and in contact wit the surface of a tooth, becomes an activator capable of accelerating tooth whitening; and

a second part comprising hydrogen peroxide;

wherein when the first and second parts are applied to a tooth, the first and second parts are sufficiently transparent to light such that about 10 to about 200 milliWatt/cm^2 of light of wavelengths between about 350 nm and about 700 nm can be applied to a tooth surface bearing the first part and the second part.

Claim 40 (Previously added) A two-part tooth whitening system according to claim 39, wherein the metal ion chelator is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DETPA), nitrilotriacetic acid (NTA), 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra(methylenephosphonice acid), and diethylenetriamine penta(methylenephosphonic acid).

Claim 41 (Previously added) A two-part tooth whitening system according to claim 39 wherein the metal ion chelator is a non-carboxylated polyhydroxy compound.

Claim 42 (Previously added) A two part tooth whitening system according to claim 41, wherein the non-carboxylated polyhydroxy compound is selected from the group consisting of sorbitol, xylitol, mannitol, maltitol, and lactitol.

Claim 43 (Previously added) A two-part tooth whitening system according to claim 39, wherein the hydrogen peroxide is present at a concentration between about 3 percent by weight to about 15 percent by weight.

1. A composition comprising:

an orally acceptable, tooth whitening peroxyacetic acid generating mixture including a source of peroxide and an acetic acid ester of glycerin, wherein the source of peroxide and the acetic acid ester of glycerin are dispersed within an anhydrous carrier.

3. The composition of claim 1 wherein the acetic acid ester of glycerin is selected from the group consisting of glyceryl triacetate, glyceryl diacetate and glyceryl acetate.

4. A composition according to claim 1, wherein the source of peroxide is selected from the group consisting of carbamide peroxide, sodium percarbonate, sodium perborate, calcium peroxide, magnesium peroxide, sodium peroxide, and anhydrous poly(vinyl pyrrolidone) / hydrogen peroxide complexes.

5. A composition according to claim 1 capable of providing an oral pH of more than 5.2 to generate peroxyacetic acid.

6. A composition according to claim 5, wherein the oral pH is 7.8.

8. The composition of claim 1 wherein the carrier is selected from the group consisting of glycerin, propylene glycol, polyethylene glycols, chewing gum and gum base products, floss carriers and floss wax products, oils, waxes and esters.

9. The composition of claim 1 further comprising a thickening agent.

10. The composition of claim 9 wherein the thickening agent is selected from the group consisting of neutralized carboxymethylene, polyacrylic acid polymers and copolymers,

hydroxypropylcellulose and other cellulose ethers, salts of poly(methyl vinyl ether-co-maleic anhydride), poly(vinylpyrrolidone), poly(vinylpyrrolidone-co-vinyl acetate), silicon dioxide, fumed silica, and stearic acid esters.

11. The composition of claim 1 further comprising a buffer.

12. The composition of claim 11 wherein the buffer is selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, polyethylenimine, polyacrylic acid, poly(methyl vinyl ether-co-maleic anhydride), citric acid, and phosphoric acid.

13. The composition of claim 1 further comprising a surfactant.

14. The composition of claim 13 wherein the surfactant is selected from the group consisting of zwitterionic and fluorinated surfactants.

15. The composition of claim 1 further comprising a chelating agent.

16. The composition of claim 15 wherein the chelating agent is selected from the group consisting of phosphonic acids, EDTA, and polyphosphates.

17. The composition of claim 1 further comprising flavorants or sweeteners.

18. (Amended) A composition for producing peroxyacetic acid for use in whitening teeth, the composition comprising a two component system including:

a first aqueous component including hydrogen peroxide and

a second component including glyceryl triacetate.

19. A method for whitening teeth comprising:

forming a composition having an oral pH in excess of about 5.2 by combining a hydrogen peroxide precursor, glyceryl triacetate, and water so as to generate peroxyacetic acid; and

applying the composition to a tooth surface.

20. A method for whitening teeth comprising:

applying one of either a glyceryl triacetate or a hydrogen peroxide releasing compound onto a tooth surface; and

applying the other of the remaining glyceryl triacetate or hydrogen peroxide releasing compound onto the same tooth surface, so as to generate peroxyacetic acid upon contact with an aqueous solution on the surface of the tooth.

21. A method for whitening teeth comprising:

providing separately glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth;

forming a mixture between the glyceryl triacetate and the hydrogen peroxide releasing compound; and

applying the mixture onto a tooth surface.

22. (Amended) A method for cosmetically treating teeth comprising the steps of:

applying a source of labile acetyl groups onto the surface of a tooth;

allowing the source of labile acetyl groups to penetrate into the tooth;

applying a source of peroxide onto the surface of the tooth;

allowing the source of labile acetyl groups to react with the source of peroxide to generate a peroxyacid within the tooth; and

allowing the peroxyacid to effect whitening of the tooth.

23. The method of claim 22 wherein the source of labile acetyl groups is a C_1-C_5 molecule having between 1 to 5 labile C_1-C_5 acyl containing groups.

24. The method of claim 22 wherein the source of labile acetyl groups has a molecular weight less than 1000.

25. The method of claim 22 wherein the source of labile acetyl groups has a molecular weight less than 500.

26. The method of claim 22 wherein the source of labile acetyl groups has a molecular weight of between about 100 to about 300.

27. The method of claim 22 wherein the source of labile acetyl groups has a molecular weight approximate that of glyceryl triacetate.

28. The composition of claim 7, wherein the carrier is chewing gum.

29. The composition of claim 7 wherein the carrier is dental floss.

42. A kit including a first tube and a second tube, the tubes adapted to keep apart two formulations, the first tube and second tube respectively include:

a first formulation comprising hydrogen peroxide and an aqueous carrier wherein the first formulation is substantially free of alkaline pH adjusting agent; and

a second formulation comprising an alkaline pH-adjusting agent and wherein the second formulation is substantially free of the hydrogen peroxide;

the first formulation or the second formulation including a thickener and whereby mixing the first formulation and the second formulation forms a thickened, aqueous, hydrogen peroxide containing mixture, wherein the mixture has a pH of greater than 5.5.

43. The kit of claim 42 wherein the mixture includes a stabilizing agent.

44. The kit of claim 42 wherein the mixture includes a calcium chelating agent.

45. The kit of claim 42 wherein the mixture has a pH within a range of between about 6 to about 10.

46. The kit of claim 42 wherein the mixture has a pH within a range of between about 7 to about 10.

47. The kit of claim 42 wherein the mixture includes at least 70% water by weight, based on the weight of the mixture.

48. The kit of claim 42 wherein the alkaline pH adjusting agent is a member selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine.

49. The kit of claim 43 wherein the stabilizing agent is a member selected from the group consisting of sodium acid pyrophosphate, sodium stannate trihydrate, and 1-hydroxyethylidene-1,1-diphosphonic acid.

50. The kit of claim 44 wherein the calcium chelating agent is a member selected from the group consisting of EDTA, salts of EDTA, citric acid, salts of citric acid, gluconic acid, salts of gluconic acid, alkali metal pyrophosphates and alkali metal polyphosphates.

51. The kit of claim 42 wherein the thickener is a high molecular weight crosslinked polyacrylic acid.

52. The kit of claim 42 wherein the mixture has a hydrogen peroxide concentration of less than 15% by weight of the mixture.

53. The kit of claim 43 wherein the stabilizing agent may also act as a calcium chelating agent.

54. The kit of claim 42 wherein the mixture has a pH within a range of between approximately 7.5 and approximately 9.0.

55. The kit of claim 42 wherein the mixture has a pH of approximately 8.0.

56. A dosage delivery unit for delivering a tooth bleaching composition comprising:

a multi-chambered vessel wherein chambers are responsive to applied pressure from an external source;

a mixing baffle in communication with the chambers such that an aqueous mixture of a hydrogen peroxide containing tooth bleaching composition exits the dosage delivery unit in response to the applied pressure on the chambers.

57. The dosage delivery unit of claim 56 wherein the aqueous mixture further comprises a thickener and an alkaline pH adjusting agent.

58. The dosage delivery unit of claim 57 wherein the aqueous mixture has a pH of greater than 5.5.

59. The dosage delivery unit of claim 57 wherein the aqueous mixture further comprises a stabilizing agent.

60. The dosage delivery unit of claim 57 wherein the aqueous mixture further comprises a calcium chelating agent.

61. The dosage delivery unit of claim 56 wherein the aqueous mixture includes at least 70% water by weight, based on the weight of the mixture.

62. The dosage delivery unit of claim 57 wherein the alkaline pH adjusting agent is a member selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS and triethanolamine.

63. The dosage delivery unit of claim 59 wherein the stabilizing agent is a member selected from the group consisting of sodium acid pyrophosphate, sodium stannate trihydrate, and 1-hydroxyethylidene-1,1-diphosphonic acid.

64. The dosage delivery unit of claim 60 wherein the calcium chelating agent is a member selected from the group consisting of EDTA, salts of EDTA, citric acid, salts of citric acid, gluconic acid, salts of gluconic acid, alkali metal pyrophosphates and alkali metal polyphosphates.

65. The dosage delivery unit of claim 57 wherein the thickener is a high molecular weight crosslinked polyacrylic acid.

66. The dosage delivery unit of claim 56 wherein the aqueous mixture has a hydrogen peroxide concentration of less than 15% by weight of the mixture.

67. The dosage delivery unit of claim 57 wherein the mixture has a pH within a range of between approximately 6.0 and approximately 10.0

68. The dosage delivery unit of claim 57 wherein the mixture has a pH within a range of between approximately 7.0 and approximately 10.0.

69. The dosage delivery unit of claim 57 wherein the aqueous mixture has a pH within a range of between approximately 8.0 and approximately 9.5.

70. The dosage delivery unit of claim 56 wherein the chambers include formulations in the form of a gel or paste.

13. A method for whitening the teeth of a subject comprising the steps of

applying to the teeth a composition having a pH of between about 7 and about 10 and comprising an alkalizing agent, and

contacting the teeth with a mixture comprising a hydrogen peroxide precursor compound in an amount effective to whiten teeth.

14. The method of claim 13 wherein the alkalizing agent is selected from the group consisting of sodium hydroxide, sodium carbonate, and ammonium carbonate.

15. The method of claim 13 wherein the composition is a rinse, paste or gel.

16. The method of claim 13 wherein the composition is buffered in a manner to maintain tooth surface pH between about 7 and about 10.

17. The method of claim 13 wherein tooth surface pH is maintained at a pH of between about 7 and about 10.

18. A method for whitening the teeth of a subject comprising the steps of

applying to the teeth a composition having a pH of between about 7 and about 10 and comprising an alkalizing agent, and

contacting the teeth with a mixture comprising hydrogen peroxide in an amount effective to whiten teeth.

19. The method of claim 18 wherein the alkalizing agent is selected from the group consisting of sodium hydroxide, sodium carbonate, and ammonium carbonate.

20. The method of claim 18 wherein the composition is a rinse, paste or gel.

21. The method of claim 18 wherein the composition is buffered in a manner to maintain tooth surface pH at between about 7 and about 10.

22. The method of claim 18 wherein tooth surface pH is maintained at a pH of between about 7 and about 10.

23. A method for whitening teeth of a subject comprising the steps of

raising tooth surface pH to between about 7 and about 10, and

contacting the tooth surface with a peroxide-containing or peroxide releasing tooth bleaching composition.

24. The method of claim 23 wherein the step of raising tooth surface pH includes applying to the teeth a composition comprising an alkalizing agent having a pH of between about 7 and about 10.

25. (Amended) The method of claim 24 wherein the alkalizing agent is selected from the group consisting of sodium hydroxide, sodium carbonate, and ammonium carbonate.

26. The method of claim 23 wherein the composition is a rinse, paste or gel.

27. The method of claim 23 wherein the composition is buffered in a manner to maintain tooth surface pH at between about 7 and about 10.

28. The method of claim 23 wherein tooth surface pH is maintained at a pH of between about 7 and about 10.

29. A method for whitening the teeth of a subject comprising the steps of

applying to the teeth a composition capable of buffering tooth surface pH at between about 7 and about 10, and

contacting the teeth with a mixture comprising a hydrogen peroxide precursor compound or hydrogen peroxide in an amount effective to whiten teeth.

30. The method of claim 29 wherein the composition capable of buffering tooth surface pH includes a member selected from the group consisting of potassium phosphate, sodium hydroxide, sodium carbonate, and ammonium carbonate.

31. The method of claim 29 wherein the composition is a rinse, paste or gel.

32. A method for whitening the teeth of a subject comprising the steps of

buffering tooth surface pH at between about 7 and about 10, and

contacting the teeth with a mixture comprising a hydrogen peroxide precursor compound or hydrogen peroxide in an amount effective to whiten teeth.

33. The method of claim 32 wherein the step of buffering include applying to the tooth surface a composition comprising a member selected from the group consisting of potassium phosphate, sodium hydroxide, sodium carbonate, and ammonium carbonate.

34. The method of claim 32 wherein the composition is a rinse, paste or gel.

35. A method for whitening the teeth of a subject comprising the steps of

maintaining tooth surface pH at between about 7 and about 10, and

contacting the teeth with a mixture comprising a hydrogen peroxide precursor compound or hydrogen peroxide in an amount effective to whiten teeth.

36. The method of claim 35 wherein the step of maintaining includes applying a composition including a member selected from the group consisting of potassium phosphate, sodium hydroxide, sodium carbonate, and ammonium carbonate.

37. The method of claim 35 wherein the composition is a rinse, paste or gel.

38. A method for whitening teeth of a subject comprising the steps of

applying to the teeth a composition comprising an alkalizing agent, and

contacting the teeth with a mixture comprising a hydrogen peroxide precursor compound in an amount effective to whiten teeth,

wherein the pH at the tooth surface is between about 7 and about 10.

39. The method of claim 38 wherein the alkalizing agent is selected from the group consisting of sodium hydroxide, sodium carbonate, and ammonium carbonate.

40. The method of claim 38 wherein the composition is a rinse, paste or gel.

41. The method of claim 38 wherein the composition is buffered in a manner to maintain tooth surface pH between about 7 and about 10.

42. The method of claim 38 wherein tooth surface pH is maintained during tooth whitening at a pH of between about 7 and about 10.

43. A method for effecting heightened whitening of teeth which comprises the sequential steps of first applying to the teeth an aqueous rinse composition having an alkaline pH of about 8.0 to about 10.5 which application is thereafter immediately followed by brushing the teeth to which the rinse has been previously applied with a peroxide dentifrice to effect whitening of the teeth without water rinsing the teeth between the rinse regimen and the dentifrice regimen.

44. The method of claim 43 wherein the teeth are brushed with the dentifrice immediately following application of the rinse.

45. The method of claim 43 wherein the peroxide is urea peroxide.

46. The method of claim 43 wherein the peroxide compound is present in the dentifrice composition at a concentration at about 1.0 to about 10% by weight of the composition.

47. The method of claim 43 wherein an abrasive is present in the dentifrice composition at a concentration of about 1 to about 30% by weight of the composition.

48. The method of claim 5 wherein the abrasive compound is calcined alumina.

49. A method for whitening the teeth of a subject comprising the steps of

applying to the teeth a composition comprising an alkalizing agent having a pH of between about 7 and about 10, and

contacting the teeth with a mixture comprising a hydrogen peroxide precursor compound in an amount effective to whiten teeth.

50. The method of claim 49 wherein the alkalizing agent is selected from the group consisting of sodium hydroxide, sodium carbonate, and ammonium carbonate.

51. The method of claim 49 wherein the composition is a rinse, paste or gel.

52. The method of claim 49 wherein the composition is buffered in a manner to maintain tooth surface pH between about 7 and about 10.

53. The method of claim 49 wherein tooth surface pH is maintained at a pH of between about 7 and about 10.

54. A method for whitening the teeth of a subject comprising the steps of

applying to the teeth a composition comprising an alkalizing agent having a pH of between about 7 and about 10, and

contacting the teeth with a mixture comprising hydrogen peroxide in an amount effective to whiten teeth.

55. The method of claim 54 wherein the alkalizing agent is selected from the group consisting of sodium hydroxide, sodium carbonate, and ammonium carbonate.

56. The method of claim 54 wherein the composition is a rinse, paste or gel.

57. The method of claim 54 wherein the composition is buffered in a manner to maintain tooth surface pH at between about 7 and about 10.

58. The method of claim 54 wherein tooth surface pH is maintained at a pH of between about 7 and about 10.

59. The method of claim 24 wherein the composition comprising an alkalizing agent is a rinse, paste or gel.

60. The method of claim 24 wherein the composition comprising an alkalizing agent is buffered in a manner to maintain tooth surface pH at between about 7 and about 10.

61. The method of claim 24 wherein tooth surface pH is maintained at a pH of between about 7 and about 10.

62. The method of claim 33 wherein the composition comprising a member selected from the group consisting of potassium phosphate, sodium hydroxide, sodium carbonate, and ammonium carbonate is a rinse, paste or gel.

63. The method of claim 36 wherein the composition including a member selected from the group consisting of potassium phosphate, sodium hydroxide, sodium carbonate, and ammonium carbonate is a rinse, paste or gel.

contents of both chambers into and through a series of mixing elements that are attached to one end of the dual chambered syringe. Such a mixing element assembly is known in the art as a static mixer. The two components thus become mixed as they are forced into one end of the static mixer, through the static mixer, and finally out the other end of the static mixer assembly. The mixture that emerges from the end of the static mixer assembly is preferably applied directly to the oral cavity, rather than being stored for an extended period of time.

[0075] In addition, two or multi-part systems may be applied in sequence, whereby one separately packaged component is applied to a surface of the oral cavity, followed by the application (to the same oral cavity surface) of a second separately packaged component to the oral cavity, etc. Mixing of the two or more components is thus accomplished in-situ, rather than prior to application.

EXAMPLE 3

[0076] Method of Preventing Tooth Sensitivity Associated with Peroxide Tooth Whitening

[0077] Most tooth whitening compositions that are capable of eliminating or reducing both extrinsic and intrinsic tooth staining contain an oxidizing compound. Typically, the oxidizing compound is either hydrogen peroxide, or a precursor to hydrogen peroxide, such as carbamide peroxide, sodium perborate, sodium percarbonate, and others. It is known that hydrogen peroxide is able to penetrate through intact enamel and dentin (and more easily through cracks in enamel or exposed root surfaces), thus reaching vital pulp tissue within 15 minutes from initial contact of the peroxide tooth whitening composition on the tooth surface. It is speculated that the presence of peroxide in the pulp chamber is one of the major contributors to tooth sensitivity associated with such tooth whitening procedures.

[0078] A particularly useful application of the inventive ascorbyl phosphate compositions is for alleviating or preventing the tooth sensitivity often associated with the use of peroxide-containing tooth whitening compositions. Upon contact with a tooth surface that has been treated with a peroxide-containing tooth whitening composition, the ascorbyl phosphate compositions provide a source of ascorbic acid upon hydrolysis by phosphatase enzymes present in the oral cavity. Ascorbic acid is known to be a powerful free-radical scavenger. While not wishing to be bound by any particular theory, release of ascorbic acid from ascorbyl phosphate applied to the oral cavity may reduce the likelihood of pulp tissue damage by scavenging free-radical degradation products of hydrogen peroxide, such as the hydroxyl radical (.OH) and the perhydroxyl radical (.OOH). An additional benefit may be obtained after hydrolysis of the ascorbyl phosphate molecule, in that free phosphate ion is released into salivary solution and at the tooth surface, thus creating conditions that are highly conducive to formation (typically by precipitation) of calcium phosphate crystals within the dentinal tubules. Blockage of the dentinal tubules is known to decrease tooth sensitivity by reducing the likelihood of fluid movement within the tubules caused by external stimuli, such as heat, cold, and contact with hygroscopic foodstuffs.

[0079] A preferred method of reducing or eliminating the tooth sensitivity associated with peroxide-based tooth whitening procedures comprises the sequential steps of

[0080] 1. Contacting a tooth surface or tooth surfaces with a peroxide-containing tooth whitening composition for a period of time in order to effect tooth whitening.

[0081] 2. Contacting the same tooth surface or tooth surfaces with a composition comprising a compound of formula I, such as an ascorbyl phosphate

[0082] Optionally, the ascorbyl phosphate compositions of the above method may contain other ingredients commonly employed in oral care formulations, such as humectants, thickeners, preservatives, foaming agents, solubilizers, adherence-enhancing agents, phosphatase enzyme inhibitors, antimicrobial agents, anticaries agents, tartar control agents, tooth desensitizing agents, sweeteners, and flavorants.

[0083] The carrier or dissemination means for the ascorbyl phosphate in the method above can be a liquid, gel, paste, cream, stick, chewing gum, or any other oral care vehicle as would be well known to those skilled in the art. The compositions of the above method may be applied or positioned into close proximity with an oral cavity surface by rinsing, brushing, spraying, or chewing. An oral cavity surface may be the surface of a tooth, the oral mucosal, the tongue, or even a surface temporarily exposed during a dental surgical procedure, such as a root canal or cavity excavation. Another means of applying the compositions of the above method onto an oral cavity surface is by placing the composition in a dental tray, on a strip, or on a patch, and then placing said dental tray, strip or patch in the oral cavity, preferably in direct contact with the oral cavity surfaces to be treated.

EXAMPLE 4

[0084] Denture Adhesive Comprising a Sodium/Calcium Mixed Salt of Ascorbyl-2-phosphate

[0085] Useful compositions have been prepared that demonstrate antioxidant activity when used as a denture adhesive to temporarily affix a denture to an oral mucosal surface. One example of such a denture adhesive is provided in the table below.

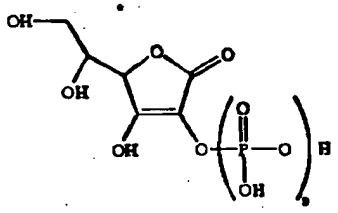
Petrolatum	31.259
Mineral Oil	14.271
Ascorbyl-2-phosphate, Na/Ca mixed salt (Rovimix Stay-C 35)	2.000
Hydrated silica	1.833
Poly(methyl vinyl ether/maleic anhydride), Na/Ca mixed salt	32.285
Cellulose Gum	18.052
Sodium Saccharin	0.100
Methyl Paraben	0.100
Propyl Paraben	0.100
Total	100.000

What is claimed:

1. An oral care composition comprising

(a) an orally acceptable carrier, and

(b) an ascorbyl-2-phosphate compound having the following structure, or a sodium or potassium salt thereof,



where n is between 1 and 10.

2. The composition of claim 1 wherein n is 2.

3. The composition of claim 1 wherein n is 3.

4. The composition of claim 1 wherein n is between 1 and 5.

5. The composition of claim 1 further including a source of calcium ions.

6. The composition of claim 1 mixed with saliva including a source of calcium ions.

7. The composition of claim 1 wherein the ascorbyl phosphate is ascorbyl-2-monophosphate, ascorbyl-2-diphosphate, ascorbyl-2-triphosphate, ascorbyl-2-polyphosphate, or combinations thereof.

8. The composition of claim 1 which optionally includes one or more of an anticaries agent, a tartar control agent, an antimicrobial agent, and a desensitizing agent.

9. The composition of claim 1 further including an ingredient promoting the adherence of the compound of formula I to the tooth or gums.

10. The composition of claim 9 wherein the ingredient is a polymer.

* * * * *

CLAIMS

What is claimed is:

1. A method of tooth whitening, comprising:

contacting a tooth surface of a patient with a tooth whitening composition having a pH between about 6.0 and about 12.0, wherein the tooth whitening composition comprises an oxidizing compound and an accelerator; and

exposing the tooth surface to light energy.

2. The method of claim 1, wherein the oxidizing compound is selected from the group consisting of hydrogen peroxide, carbamide peroxide, alkali metal peroxides, alkali metal percarbonates, and alkali metal perborates.

3. The method of claim 1, wherein the oxidizing compound comprises at least one of a peroxyacid compound or a peroxyacid precursor.

4. The method of claim 3, wherein the peroxyacid precursor is selected from the group consisting of glyceryl triacetate, acetylated amino acids, acetylsalicylic acid, and N,N,N',N'-tetraacetyl ethylenediamine, vinyl acetate polymers and copolymers, acetylcholine, and other biologically acceptable acetylated compounds.

5. The method of claim 1, wherein the accelerator comprises an alkaline pH adjusting agent.

6. The method of claim 5, wherein the alkaline pH adjusting agent is selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, and polyethylenimine.

7. The method of claim 1, wherein the tooth whitening composition further comprises a thickener.

8. The method of claim 7, wherein the thickener is selected from the group consisting of carboxypolymethylene, polyacrylic acid polymers and copolymers, hydroxypropylcellulose, cellulose ethers, salts of poly(methyl vinyl ether-co-maleic anhydride), polyvinyl pyrrolidone, poly(vinylpyrrolidone-co-vinyl acetate), silicon dioxide, fumed silica, and stearic acid esters.

9. The method of claim 5, wherein the accelerator further comprises a buffer.

10. The method of claim 9, wherein the buffer comprises gylcine.

11. The method of claim 5, wherein the accelerator further comprises a surfactant.

12. The method of claim 11, wherein the surfactant comprises a zwitterionic surfactant.

13. The method of claim 11, wherein the surfactant comprises glycine.

14. A method of tooth whitening, comprising:

contacting a tooth surface of a patient with an accelerator composition having a pH between about 6.0 and about 12.0;

sequentially contacting the accelerator-treated tooth surface with an oxidizing composition; and

thereafter exposing the tooth surface to light energy.

15. The method of claim 14, wherein the oxidizing composition comprises an oxidizing compound.

16. The method of claim 15, wherein the oxidizing compound is selected from the group consisting of hydrogen peroxide, carbamide peroxide, alkali metal peroxides, alkali metal percarbonates, and alkali metal perborates.

17. The method of claim 15, wherein the oxidizing compound comprises at least one of a peroxyacid compound or a peroxyacid precursor.

18. The method of claim 17, wherein the peroxyacid precursor is selected from the group consisting of glyceryl triacetate, acetylated amino acids, acetylsalicylic acid, and N,N,N',N'-tetraacetyl-ethylenediamine, vinyl acetate polymers and copolymers, acetylcholine, and other biologically acceptable acetylated compounds.

19. The method of claim 15, wherein the accelerator composition comprises an alkaline pH adjusting agent.

20. The method of claim 19, wherein the alkaline pH adjusting agent is selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, and polyethylenimine.

21. The method of claim 14, wherein at least one of the accelerator composition and the oxidizing composition comprise a thickener.

22. The method of claim 21, wherein the thickener is selected from the group consisting of carboxypolymethylene, polyacrylic acid polymers and copolymers, hydroxypropylcellulose, cellulose ethers, salts of poly(methyl vinyl ether-co-maleic anhydride), polyvinyl pyrrolidone, poly(vinylpyrrolidone-co-vinyl acetate), silicon dioxide, fumed silica, and stearic acid esters.

23. The method of claim 19, wherein the accelerator composition further comprises a buffer.

24. The method of claim 23, wherein the buffer comprises gylcine.

25. The method of claim 23, wherein the accelerator composition comprises potassium hydroxide and glycine.

26. The method of claim 19, wherein the accelerator composition further comprises a surfactant.

27. The method of claim 26, wherein the surfactant comprises a zwitterionic surfactant.

28. The method of claim 27, wherein the surfactant comprises glycine.

29. The method of claim 14, wherein the accelerator composition comprises a photosensitive agent.

30. The method of claim 29, wherein the photosensitive agent comprises a metal-ligand complex that absorbs light in the range of from about 350 nm to about 700 nm.

31. The method of claim 30, wherein the metal-ligand complex comprises ferrous chloride.

32. The method of claim 29, wherein the photosensitive agent comprises a chelator.

33. The method of claim 32, wherein the chelator is selected from the group consisting of ethylenediamine tetraacetic acid, diethylenetriamine pentaacetic acid, nitrilotriacetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra(methylenephosphonic acid), and diethylenetriamine penta(methylenephosphonic acid),.

34. The method of claim 29, wherein the photosensitive agent is selected from the group consisting of sorbitol, xylitol, mannitol, maltitol, lactitol and other non-carboxylated polyhydroxy compounds

35. The method of claim 29, wherein the photosensitive agent comprises 1-hydroxyethylidene-1,1-diphosphonic acid and ferrous chloride.

36. The method of claim 19, wherein the accelerator composition further comprises a photosensitive agent.

37. The method of claim 15, wherein the oxidizing compound is present in an amount of from about 1.0 % to about 40.0% by weight of the oxidizing composition.

38. The method of claim 15, wherein the oxidizing compound is present in an amount of from about 10.0 % to about 20.0% by weight of the oxidizing composition.

39. The method of claim 15, wherein the oxidizing compound is present in an amount of from about 20.0 % to about 30.0% by weight of the oxidizing composition.

40. The method of claim 15, wherein the oxidizing compound is present in an amount of from about 30.0 % to about 40.0% by weight of the oxidizing composition.

41. The method of claim 19, wherein the alkaline pH adjusting agent is present in an amount of from about 0.1 % to about 90.0 % by weight of the accelerator composition.

42. The method of claim 19, wherein the alkaline pH adjusting agent is present in an amount of from about 1.0 % to about 20.0 % by weight of the accelerator composition.

43. The method of claim 19, wherein the alkaline pH adjusting agent is present in an amount of from about 1.0 % to about 10.0 % by weight of the accelerator composition.

44. The method of claim 14, wherein the oxidizing composition comprises hydrogen peroxide and wherein the accelerator composition comprises potassium hydroxide, glycine, polyvinyl pyrrolidone, and water.

45. The method of claim 14, wherein the oxidizing composition comprises hydrogen peroxide and wherein the accelerator composition comprises 1-hydroxyethylidene-1,1-diphosphonic acid, ferrous chloride, and water.

46. A composition for accelerating whitening teeth, comprising:

an alkaline pH adjusting agent;

an aqueous carrier; and

at least one performance enhancing adjuvant.

47. The composition of claim 46, wherein the alkaline pH adjusting agent is selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, and polyethylenimine.

48. The composition of claim 46, wherein the at least one performance enhancing adjuvant is selected from the group consisting of a buffer, a surfactant, a thickener, a film-forming ingredient, a penetration enhancer, and a desensitizing agent.

Pending Claims in 04163-00162 (Cont. of 09/237,191)

1. An oral care composition for activating a peroxidase system in an animal oral cavity, comprising:

a non-aqueous or other wise substantially water-free dentifrice;

non-enzymatic, water-soluble, finely divided hydrogen peroxide precursor material incorporated within the dentifrice, the material capable of rapidly releasing an effective amount of hydrogen peroxide for activating the peroxidase system in the oral cavity upon contact with an aqueous solution, the material coated or encapsulated by being dispersed in a water insoluble, non-hygroscopic, viscous fluid or in a film-forming, melt-processable waxy solid, the fluid or solid selected from the group consisting of:

(a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or

(b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcohols, the fluid or solid being a non-solvent of the material; and

a pH-adjusting agent capable of producing a selected pH of between about 4.0 and about 6.5 in the aqueous solution.

2. A composition according to claim 1, wherein the material is finely divided sodium percarbonate.

3. A composition according to claim 1, wherein the material is finely divided carbamide peroxide.

4. A composition according to claim 1, wherein the material is finely divided calcium peroxide.

5. A composition according to claim 1, further comprising an abrasive.

6. A composition according to claim 1, further comprising a flavorant.

7. A composition according to claim 1, further comprising a thickener.

8. A composition according to claim 1, further comprising an alkali metal thiocyanate.

9. A composition according to claim 1, further comprising a peroxidase enzyme.

10. A process for manufacturing an oral care composition, comprising:

obtaining non-enzymatic, water-soluble, finely divided hydrogen peroxide precursor material,

providing a non-aqueous or otherwise substantially water-free dentifrice,

dispersing the finely divided hydrogen peroxide precursor material in a water insoluble, non-hygroscopic, viscous fluid or in a film-forming, melt-processable, waxy solid, the fluid or solid selected from the group consisting of:

(a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or

(b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcohols, the fluid or solid being a non-solvent of the finely divided hydrogen peroxide precursor material, so as to coat or encapsulate the finely divided hydrogen peroxide precursor material,

associating the finely divided hydrogen peroxide precursor material with a pH-adjusting agent capable of producing a selected pH of between about 4.0 and about 6.5 in an aqueous solution, and

incorporating the associated material within the dentifrice.

11. A method of activating a peroxidase system in an oral cavity of an animal, comprising:

selecting non-enzymatic, water-soluble, finely divided hydrogen peroxide precursor material capable of rapidly releasing an effective amount of hydrogen peroxide for

activating the peroxidase system in the oral cavity upon contact with an aqueous solution, the material coated or encapsulated by being dispersed in a water insoluble, non-hygroscopic, viscous fluid or in a film-forming, melt-processable, waxy solid, the fluid or solid selected from the group consisting of:

(a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or

(b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcohols, the fluid or solid being a non-solvent of the material,

mixing the material with a pH-adjusting agent capable of producing a selected pH of between about 4.0 and about 6.5 in the aqueous solution, and

administering to the oral cavity, the material and pH-adjusting agent incorporated within a non-aqueous or otherwise substantially water-free dentifrice.

Liquid Binder	Amount
Ethyl methacrylate	(84.00 – X)%
Hydroxyethyl methacrylate	10.00
Ethylene glycol dimethacrylate	6.00
N,N-dimethyl-p-toluidine	X
Total	100.00

Polymeric Filler

Poly(ethyl-co-methyl methacrylate) (70:30 mole ratio)	(100.00 – Y)%
Benzoyl peroxide	Y
Total	100.00

Polymerization

Example	X	Y	Time (seconds)	Yellowing
Q	1.00	1.40	200	7
R	0.80	1.12	210	6
S	0.60	0.84	270	5
T	0.40	0.56	500	3

A comparison of Examples P and S above, which utilize the same levels of benzoyl peroxide and N,N-dimethyl-p-toluidine, effectively demonstrates the accelerating properties of the hydroxyl-containing compound, hydroxyethyl methacrylate. Thus, faster polymerization times are obtainable by the present inventive compositions at given levels of organic peroxide and tertiary amine, and, conversely, less yellowing is observed at equivalent polymerization times, as evidenced by a comparison of Examples S and L.

The following example represents a preferred embodiment of the present invention.

Liquid Binder	Amount
Ethyl methacrylate	82.20%
Hydroxyethyl methacrylate	10.00
Ethylene glycol dimethacrylate	6.00
N,N-dimethyl-p-toluidine	0.80
Tinuvin P	1.00
Total	100.00%

Polymeric Filler

Poly(ethyl-co-methyl methacrylate) (70:30 mole ratio)	98.88%
Benzoyl peroxide	1.12
	100.00%

The composition above, when combined in a ratio of 1.00 parts liquid binder to 2.70 parts polymeric filler, has a polymerization time of 210 seconds and a yellowing index score of 2.

Also contemplated within the scope of the present invention are compositions similar to the examples outlined above, but intended for use as self-polymerizing dental polymers, such as those utilized for denture, crown and bridge work.

What is claimed is:

1. An artificial fingernail composition consisting essentially of:

(i) a liquid binder, by total weight:

(a) from about 10 percent to about 95 percent of a methacrylate monomer selected from the group consisting of ethyl methacrylate, n-butyl methacrylate, isobutyl methacrylate, n-propyl methacrylate, isopropyl methacrylate, tert-butyl methacrylate, and combinations thereof,

(b) from about 1 percent to about 50 percent of a saturated alcohol compound selected from the group consisting of hydroxypropyl methacrylate, hydroxybutyl methacrylate, propylene glycol monomethyl ether, diethylene glycol monomethyl ether, isopropyl alcohol, propylene glycol, 1,4-butylene glycol, neopentyl glycol monomethacrylate, and combinations thereof,

(c) from about 0.1 percent to about 5.0 percent of a tertiary amine polymerization accelerator, selected from the group consisting of N,N-dimethyl-p-toluidine, N,N-dihydroxyethyl-p-touidine, N,N-dimethyl aniline, and 4-(dimethylamino)phenethyl alcohol, and

(d) from about 1 percent to about 80 percent of a di-,tri-, or multi-functional methacrylate crosslinker selected from the group consisting of ethylene allyl dimethacrylate, diethylene glycol dimethacrylate, triethylene glycol dimethacrylate, tetraethylene glycol dimethacrylate,. poly(ethylene glycol) dimethacrylate, 1,3-butanediol dimethacrylate, 1,4-butanediol dimethacrylate, 1,6-hexanediol dimethacrylate, 1,12-dodecanediol dimethacrylate, neopentyl glycol dimethacrylate trimethylolpropane trimethacrylate, and combinations thereof; and

(ii) a polymeric filler portion , by dry weight of filler:

(a) from about 95 percent to about 99.9 percent of a finely divided polymer selected from the group including, but, not limited to, poly(ethyl methacrylate), poly(methyl methacrylate), poly (ethyl-co-methyl methacrylate), poly(butyl methacrylate), poly(methyl-co-butyl methacrylate), poly(vinyl acetate), poly(vinyl butyral) and poly (ethyl-co-butyl methacrylate) and mixtures thereof,

(b) from about 0.1 percent to about 5.0 percent of an organic peroxide polymerization initiator.

2. The artificial fingernail composition of claim 1, said liquid binder further consisting of one of butylated hydroxytoluene (BHT) and methyl ether of hydroquinone (MEHQ).

3. The artificial fingernail composition of claim 1, said liquid binder further consisting of one of ultraviolet light stabilizers 2(2'-hydroxy-5'-methyl phenyl) benzotriazole and 2-hydroxy-4-methoxybenzophenone.

4. The artificial fingernail composition of claim 1, said liquid binder further consisting of a dye.

5. The artificial fingernail composition of claim 1, said polymeric filler portion further consisting of additives selected from pigments, secondary polymers, and flow modifiers.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,738,843
DATED : April 14, 1998
INVENTOR(S) : Montgomery

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [21], Application Number, please delete "818,903" and insert -- 08/818,903 --.

Item [63], **Related U.S. Application Data,** please delete Ser. No. "841,429" and insert -- 07/841,429 --.

Column 8,
Line 31, please delete "ethylene allyl" and insert -- ethylene glycol --.

Signed and Sealed this

Second Day of April, 2002

Attest:

Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

of curvature for the tray's surfaces 110 and 115 be less than 2.5 centimeters.

FIG. 3 is a side cross-sectional view of the duplex dental tray of FIG. 1 along line 3—3. FIG. 3 also shows the anterior curved surface 100 and a posterior curved surface 115 being connected to opposite sides of connector 130. FIG. 4 is a front view of the duplex dental tray of the present invention when worn by a person. In FIG. 4, teeth 300 are in the duplex dental tray 305.

FIG. 5 is a top cross-sectional view of the duplex dental tray of FIG. 4 along line 5—5. FIG. 5 also illustrates the insertion of the duplex dental tray 305 onto the teeth 300. As can be seen in FIG. 5, the duplex dental tray 305 before being placed onto the teeth 300 is curved more than the jaw. Once placed on the teeth 300, the duplex dental tray 305 is bent so as to conform to the curvature of the jaw. The flexing of the duplex dental tray 305 in order to conform it to the curvature of the jaw creates tension at the points indicated by the arrows 500 since the duplex dental tray is elastic and therefore resists the decrease in curvature. The tension created by the tray's elasticity helps support the tray in its position when worn as the tension pushes the tray against the patient's teeth. This tension also ensures contact of the buccal tooth surfaces with the composition placed in the upper and lower dental trays.

FIG. 6 is a side cross-sectional view of the duplex dental tray of FIG. 4 along line 6—6. In FIG. 6, tooth 600 is in the upper dental tray of the duplex dental tray which is defined by the upper anterior segment 105, the upper posterior segment 120 and the connector 130. Tooth 605 is in the lower dental tray of the duplex dental tray which is defined by the lower anterior segment 110, the lower posterior segment 125 and the connector 130. The bleaching agent 610, which is preferably a peroxide gel (such as, for example, the peroxide gel described in U.S. Pat. No. 5,290,566, or alternatively a composition described in concurrently filed provisional application entitled "Improved Method of Whitening Teeth" for an invention by Robert E. Montgomery and bearing attorney docket number 1910/110) occupies the space between the teeth and the duplex dental tray.

Also contemplated to be within the scope of the present invention is the use of the flexible tray as a reservoir for dentally therapeutic compositions, such as fluoride gels.

The above description of the drawings provides details of the preferred embodiment of the present invention. It is of course apparent that the present invention is not limited to the detailed description set forth above. Various changes and modifications of this invention as described will be apparent to those skilled in the art without departing from the spirit and scope of this invention as defined in the following claims.

What is claimed is:

1. A method of bleaching teeth of a user comprising:

providing a dental tray having two surfaces, each surface having a radius of curvature different from that of a dentition of the user, and a connector joining the two surfaces, wherein the connector and the surfaces are integrally molded to define an upper trough and a lower trough, each with a radius of curvature different from that of the dentition of the user, so that, when the tray is inserted into the user's mouth, the surfaces apply pressure against tooth surfaces of the user;

depositing a tooth bleaching composition within the upper and lower troughs of the tray; and

placing the tray and bleaching composition in the user's mouth.

2. A method as set forth in claim 1, wherein in the step of providing, the radius of curvature of each of the upper and lower troughs is smaller than that of the dentition of the user.

3. A method of therapeutically treating teeth of a user comprising:

providing a dental tray having two surfaces, each surface having a radius of curvature different from that of a dentition of the user, and a connector joining the two surfaces, wherein the connector and the surfaces are integrally molded to define an upper trough and a lower trough, each with a radius of curvature different from that of the dentition of the user, so that, when the tray is inserted into the user's mouth, the surfaces apply pressure against tooth surfaces of the user;

depositing a dentally therapeutic composition within the upper and lower troughs of the tray; and

placing the tray and dentally therapeutic composition in a patient's mouth.

4. A method as set forth in claim 3, wherein in the step of providing, the radius of curvature of each of the upper and lower troughs is smaller than that of the dentition of the user.

5. A method of bleaching teeth comprising:

(a) providing a flexible duplex tray having:

an anterior surface having a radius of curvature smaller than that of the dentition of a patient and comprising an anterior upper segment and an anterior lower segment;

a posterior surface having a radius of curvature smaller than that of the dentition of the intended patient and comprising a posterior upper segment and a posterior lower segment; and

a connector integrally molded with the anterior and posterior surfaces;

wherein the anterior surface is curved towards the posterior surface while the posterior surface is curved away from the anterior surface and further wherein the anterior surface is spaced a distance away from the posterior surface, such that the anterior upper segment and the posterior upper segment form an upper dental trough, while the anterior lower segment and the posterior lower segment form a lower dental trough;

(b) depositing a tooth bleaching composition within both the upper and lower dental troughs of the flexible duplex tray; and

(c) placing said flexible duplex tray and bleaching composition in a patient's mouth.

6. A method of therapeutically treating teeth comprising:

(a) providing a flexible duplex tray having:

an anterior surface having a radius of curvature smaller than that of the dentition of a patient and comprising an anterior upper segment and an anterior lower segment;

a posterior surface having a radius of curvature smaller than that of the dentition of the intended patient and comprising a posterior upper segment and a posterior lower segment; and

a connector integrally molded with the anterior and posterior surfaces;

wherein the anterior surface is curved towards the posterior surface while the posterior surface is curved away from the anterior surface and further wherein the anterior surface is spaced a distance away from the posterior surface, such that the anterior upper segment and the posterior upper segment form an upper dental trough, while the anterior lower

segment and the posterior lower segment form a lower dental trough;

(b) depositing a dentally therapeutic composition within both the upper and lower dental troughs of the flexible duplex tray; and

(c) placing said flexible duplex tray and dentally therapeutic composition in a patient's mouth.

7. A method of bleaching teeth of a user comprising:

providing a dental tray integrally molded from a resilient, flexible thermoplastic material and defining an upper trough and a lower trough, each having an anterior portion and a posterior portion, each portion having a radius of curvature different from that of the dentition of the user, such that when the tray is inserted into the user's mouth, the portions apply pressure against tooth surfaces of the user;

depositing a tooth bleaching composition within the upper and lower troughs of the tray; and

placing the tray and bleaching composition in the user's mouth.

8. A method of therapeutically treating teeth of a user comprising:

providing a dental tray integrally molded from a resilient, flexible thermoplastic material and defining an upper trough and a lower trough, each having an anterior portion and a posterior portion, each portion having a radius of curvature different from that of the dentition of the user, such that when the tray is inserted into the user's mouth, the portions apply pressure against tooth surfaces of the user;

depositing a dentally therapeutic composition within the upper and lower troughs of the tray; and

placing the tray and dentally therapeutic composition in a patient's mouth.

9. A method of bleaching teeth comprising:

(a) providing a flexible duplex tray having:

an anterior surface having a radius of curvature different than that of the dentition of a user and comprising an anterior upper segment and an anterior lower segment;

a posterior surface having a radius of curvature smaller than that of the dentition of the user and comprising a posterior upper segment and a posterior lower segment; and

a connector joining the anterior and posterior surfaces and having a width larger than that of the dentition of the user;

wherein the anterior surface is curved towards the posterior surface while the posterior surface is curved away from the anterior surface and further wherein the anterior surface is spaced from the posterior surface by a distance of the width of the connector, such that the anterior upper segment and the posterior upper segment form an upper dental trough, while the anterior lower segment and the posterior lower segment form a lower dental trough;

(b) depositing a tooth bleaching composition within both the upper and lower dental troughs of the flexible duplex tray; and

(c) placing said flexible duplex tray and bleaching composition in a patient's mouth.

10. A method of therapeutically treating teeth comprising:

(a) providing a flexible duplex tray having:

an anterior surface having a radius of curvature different than that of the dentition of a user and comprising an anterior upper segment and an anterior lower segment;

a posterior surface having a radius of curvature smaller than that of the dentition of the user and comprising a posterior upper segment and a posterior lower segment; and

a connector joining the anterior and posterior surfaces and having a width larger than that of the dentition of the user;

wherein the anterior surface is curved towards the posterior surface while the posterior surface is curved away from the anterior surface and further wherein the anterior surface is spaced from the posterior surface by a distance of the width of the connector, such that the anterior upper segment and the posterior upper segment form an upper dental trough, while the anterior lower segment and the posterior lower segment form a lower dental trough;

(b) depositing a dentally therapeutic composition within both the upper and lower dental troughs of the flexible duplex tray; and

(c) placing said flexible duplex tray and dentally therapeutic composition in a patient's mouth.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,816,802

DATED : October 6, 1998

INVENTOR(S) : Montgomery

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, item [73] should read:

Assignees: R. Eric Montgomery; Idex Dental Sciences, Inc., both of Monterey, Mass.

Signed and Sealed this

Second Day of February, 1999

Attest:

Attesting Officer

Acting Commissioner of Patents and Trademarks

TABLE 3-continued

EXAMPLE 1D (MG/LITER)	H_2O_2 (theoretical) (MICROMOLES/LITER)	H_2O_2 (actual) (MICROMOLES/LITER)	pH	OSCN (MICROMOLES/LITER) NO ADDED SCN-	OSCN (MICROMOLES/LITER) SCN- @ 1 MILLIMOLAR
6,000	4,764	3,890	6.25	301	690
10,000	7,941	6,920	6.25	233	662
20,000	15,882	13,202	6.26	110	272
40,000	31,764	29,990	6.25	93	160
100,000	79,410	78,540	6.25	37	90

Example III:

Hypothiocyanite ion concentrations resulting from an oral composition on chewing gum

The composition of sample 1D was applied to the surface of 3.0 gram sticks of chewing gum at a coating rate of 0.05% by weight of gum in order to produce chewing gum which was capable of generating hydrogen peroxide upon contact with saliva, in addition to providing for a salivary pH adjustment to about 6.0.

One stick of Sample 1D-coated chewing gum (3.05 grams) was broken into small pieces and vortexed with 3.05 grams of distilled water for 15 seconds. At exactly the 15 second point, a sample of the resulting fluid was assayed for hydrogen peroxide and pH as in Example I. The fluid contained a hydrogen peroxide concentration of 360 micromolar and the fluid pH was 6.03.

Saliva samples from five subjects, ages 25–45, were collected as above, but rather than being pooled, were assayed individually for hypothiocyanite ion concentrations. The results are recorded below. The same volunteers were then asked to chew the coated chewing gum samples for a period of 2 minutes. Their saliva was collected again, and their salivary hypothiocyanite ion levels recorded. (Table 4). The results show a remarkable ability of the inventive composition to impart salivary peroxidase-activating properties to the chewing gum.

TABLE 4

SUBJECT	OSCN BEFORE	OSCN AFTER
1	29 micromolar	214 micromolar
2	56 micromolar	198 micromolar
3	45 micromolar	260 micromolar
4	39 micromolar	252 micromolar
5	28 micromolar	208 micromolar

Example IV:

Hydrogen peroxide concentrations resulting from an oral composition on a rawhide chew

A rawhide animal chew was prepared by taking 10 pounds of dried, unbasted rawhide chews, approximately 2 inches wide by 6 inches in length, and spray coating them at a 1.0 percent coating rate with the following composition,

TABLE 5

COMPONENT	AMOUNT
Light Mineral Oil USP	87 grams
Sodium Percarbonate (Solvay - FB100)	10 grams
Malic Acid (Powder FCC)	3 grams
TOTAL	100 grams

The above components were slurried until a fine dispersion of solids was obtained. Agitation continued during the spray process to prevent the settling out of the solids. The sprayed rawhide chews were dried at room temperature for 24 hours, during which time the initial surface gloss observed on the freshly sprayed chews disappeared.

In order to determine the ability of the spray-coated rawhide chew to generate pH- adjusted hydrogen peroxide upon contact with water, single chews cut into four pieces and weighed. An equivalent amount of distilled water was weighed out and the coated chews vortexed in the water for 15 seconds. The "chew fluid" contained a hydrogen peroxide concentration of 6.53 millimolar at a pH of 5.84 at 25° C.

Example V:

Delivery of the oral composition in a gel

An anhydrous carbamide peroxide gel composition was prepared in order to demonstrate another option for delivery of the composition to the oral cavity.

TABLE 6

COMPONENT	AMOUNT
Glycerine 99.7% USP	93.45 grams
Carbopol 980 NF (BF Goodrich)	2.00 grams
Carbamide Peroxide (Degussa) USP	0.05 grams
Distilled Water	3.00 grams
Tris(hydroxymethyl)aminomethane USP	1.50 grams
TOTAL	100 grams

The Carbopol 980 NF was dispersed under high shear in the Glycerine 99.7% USP and subsequently deaerated. The Carbamide Peroxide was then dissolved in this mixture under low shear mixing. The Tris(hydroxymethyl) aminomethane was dissolved in the Distilled Water, and this phase dispersed into the main phase under 28" Hg vacuum in order to avoid entrapment of air. The resulting gel was highly viscous and transparent.

In the above composition, the tris (hydroxymethyl) aminomethane USP serves as both a neutralizer for thickening the acidic carboxypolymethylene (Carbopol 980 NF) and as an alkalizer to provide a suitable peroxidase-active pH during the use of this product. The pH of a 1:5 dilution (1 part Example V to 5 parts Distilled Water) is 5.4, and the dilution showed a hydrogen peroxide concentration of 969 micromoles per liter.

I claim:

1. An oral care composition for activating a peroxidase system in an animal oral cavity, comprising:

a dry, non-aqueous or otherwise substantially water-free chewable carrier selected from the group consisting of chewing gum and animal rawhide chew;

alkali metal percarbonate particles deposited on or within the carrier and acting as a

oxidase system in the oral cavity upon contact with an aqueous solution, the percarbonate particles coated or encapsulated by being dispersed in a water insoluble, non-hygroscopic, viscous fluid or in a film-forming, melt-processable waxy solid, the fluid or solid selected from the group consisting of:

(a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or (b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcobols, the fluid or solid being a non-solvent of the percarbonate particles; and

a pH-adjusting agent capable of producing a selected pH of between about 4.0 and about 6.5 in the aqueous solution for facilitating the rapid release of the hydrogen peroxide from the alkali metal percarbonate, and the activation of the peroxidase enzyme in the oral cavity.

2. The composition of claim 1, wherein the alkali metal percarbonate is sodium percarbonate.

3. A process for manufacturing an oral care composition, comprising:

(a) obtaining particles of an alkali metal percarbonate;

(b) providing a dry, non-aqueous or otherwise substantially water-free chewable carrier selected from the group consisting of chewing gum and animal rawhide chew;

(c) dispersing the percarbonate particles in a water insoluble, non-bygroscopic, viscous fluid or in a film-forming, melt-processable waxy solid, the fluid or solid selected from the group consisting of: (a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or (b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcobols, the fluid or solid being a non-solvent of the percarbonate particles, so as to coat or encapsulate the percarbonate particles;

(d) associating the percarbonate particles with a pH-adjusting agent, that is capable of producing a selected pH of between about 4.0 and about 6.5 in an aqueous solution; and

(e) depositing the associated particles on or within the carrier.

4. A method of activating a peroxidase system in an oral cavity of an animal, comprising:

(a) selecting alkali metal percarbonate particles capable of rapidly releasing an effective amount of hydrogen peroxide for activating the peroxidase system in the oral cavity upon contact with an aqueous solution, the percarbonate particles coated or encapsulated by being dispersed in a water insoluble, non-bygroscopic, viscous fluid or in a film-forming, melt-processable waxy solid, the fluid or solid selected from the group consisting of:

(a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or (b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcobols, the fluid or solid being a non-solvent of the percarbonate particles,

(b) mixing the particles with a pH-adjusting agent capable of producing a selected pH in the aqueous solution for facilitating the rapid release of the hydrogen peroxide and the activation of the peroxidase enzyme in the oral cavity, and

(c) administering to the oral cavity, the precursor and pH-adjusting agent deposited on or within a dry, non-aqueous or otherwise substantially water-free chewable carrier selected from the group consisting of chewing gum and animal rawhide chew.

5. An oral care composition according to claim 1, wherein the alkali metal percarbonate has a concentration of less than about 0.1% by weight of the total composition.

6. A process for manufacturing an oral care composition according to claim 3, wherein the alkali metal percarbonate has a concentration of less than about 0.1% by weight of the total composition.

7. A method of activating a peroxidase system in an oral cavity of an animal according to claim 4, wherein the alkali metal percarbonate has a concentration of less than about 0.1% by weight of the total composition.

8. A process for manufacturing an oral care composition according to claim 3, wherein the alkali metal percarbonate is sodium percarbonate.

9. A method of activating a peroxidase system in an oral cavity of an animal according to claim 4, wherein the alkali metal percarbonate is sodium percarbonate.

* * * * *

Sarcina lutea, for a period of about four days). Each stained bovine incisor was numbered and measured for degree of staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer (3 mm aperture, 8 exposure averaging, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes, whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below as ΔE. Absolute color change is defined as the square root of the sum of the squares of all color components (L, a, and b).

$$\sqrt{[(\Delta L)^2+(\Delta a)^2+(\Delta b)^2]}=\Delta E$$

TABLE 4

		pH	Initial Color			Final Color			
Tooth #	Product/Example	(peat)	L	a	b	L	a	b	ΔE
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5(2) to 6.0(3) results in an increased ΔE from 4.29 to 6.27.

The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating agent. There was an observed improvement in ΔE in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

Opalescence is a commercial product which has been pH adjusted to pH 6.5 before use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that the pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

EXAMPLE 5

In vivo demonstration of tooth bleaching

Six volunteers aged 25 to 43 were separated into two groups of two and custom dental trays were fashioned for each participant in the study.

One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

Patient		Treatment	Initial Color			Final Color			
#	Product/Example	Time (minutes)	L	a	b	L	a	b	ΔE
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65
4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

The average ΔE for the Example IB group was 7.32, whereas the average ΔE for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

I claim:

1. A method for bleaching a tooth surface, comprising:

providing a composition consisting essentially of

hydrogen peroxide, and

a matrix for carrying the hydrogen peroxide, the matrix having

a water content greater than 70% by weight, based on the weight of the composition,

a thickening agent,

an alkaline pH adjusting agent, and

a calcium chelating agent,

wherein the pH of the composition during the bleaching process is substantially constant within a range of 6.0–10.0; and

applying the composition to the tooth surface.

2. The method according to claim 1, wherein the water content is at least 75% by weight, based on the weight of the composition.

3. The method according to claim 1, further including placing the composition in a dental tray prior to applying the composition to the tooth surface.

4. The method according to claim 1, wherein the matrix is sufficiently pure in order to avoid peroxide destabilization by metal ion contaminants, so as to permit packaging as a one-component system.

5. The method according to claim 1, wherein the composition has a pH in the range of 7.0 –10.0.

6. The method according to claim 5, wherein the water content is at least 75% by weight, based on the weight of the composition.

7. A method for bleaching a tooth surface, comprising:

providing a composition containing

hydrogen peroxide, and

a matrix carrying the hydrogen peroxide, the matrix having

a water content greater than 70% by weight, base on the weight of the composition,

a thickening agent,

a pH adjusting agent, and

a calcium chelating agent,

wherein the pH of the tooth-bleaching composition during the bleaching process is substantially constant within a range of 6.0–10.0;

Packing the composition as a one-component system wherein the matrix is sufficiently pure in order to avoid peroxide destabilization by metal ion contaminants; and applying the composition to the tooth surface.

8. The method according to claim 7, wherein the water content is at least 75% by weight, based on the weight of the composition.

9. The method according to claim 8, further including:

placing the composition in a dental tray prior to applying the composition to the tooth surface.

10. The method according to claim 9, wherein the composition has a pH in the range of 7.0 –10.0.

* * * * *

TABLE 1

Bovine		Initial Color			Final Color			
Incisor #	Treatment	L	a	b	L	a	b	ΔE
1	CDP only	45.38	3.68	10.42	47.11	3.21	10.09	1.82
2	ACD only	54.50	-1.80	0.90	56.10	-1.90	1.40	1.68
3	CDP/ACD	42.78	3.60	11.30	48.57	1.85	10.03	6.16
4	CDP/ACD	38.27	5.31	11.08	46.51	4.61	13.91	8.55
5	CDP/ACD	35.62	4.46	9.48	38.94	3.65	9.60	3.42
6	CDP/ACD	40.91	3.94	11.08	44.30	3.07	10.22	3.69
7	CDP/ACD	43.55	3.51	10.09	48.92	2.02	9.54	5.83

This table demonstrates that the inventive compositions, when applied as described above, are effective in removing tooth stains in an vitro stained bovine enamel model. The observed tooth whitening effect is much greater, when the CDP and ADP portions are both applied, than when either just the CDP Portion or the ACD Portion is applied.

What is claimed is:

1. A method for oxidizing tooth-staining chromogens to whiten teeth, the method comprising:

(a) providing a first formulation having a chlorine dioxide precursor, the first formulation having a pH greater than approximately 7.0, and a second formulation having an acidulant capable of generating chlorine dioxide upon contact with the precursor, the second formulation being a gel having a gel pH of between approximately 3.0 and approximately 6.0;

(b) applying the first formulation to a tooth in a subject's mouth;

(c) putting the second formulation into a dental tray;

(d) inserting the dental tray containing the second formulation into the subject's mouth, so as to generate a chlorine dioxide film at an interface between the precursor and the acidulant proximate the tooth; and

(e) removing the dental tray after the tooth has been exposed to chlorine dioxide generated proximate to the tooth for a time period of between approximately five minutes and approximately sixty minutes.

2. A method according to claim 1, wherein the first formulation is a liquid, the liquid having a liquid pH.

3. A method according to claim 2, wherein the chlorine dioxide precursor is an alkali metal chlorite.

4. A method according to claim 3, wherein the chlorine dioxide precursor is sodium chlorite.

5. A method according to claim 4, wherein the liquid pH is between approximately 7.5 and approximately 9.0.

6. A method according to claim 5, wherein the liquid is aqueous.

7. A method according to claim 1, wherein the second formulation has an aqueous carrier and a polymeric, water soluble acidulant, the acidulant having a molecular weight greater than approximately 100,000.

8. A method according to claim 2, wherein the second formulation has an aqueous carrier and a polymeric, water soluble acidulant, the acidulant having a molecular weight greater than approximately 100,000.

9. A method according to claim 1, wherein the acidulant is selected from the group consisting of citric acid, carboxypolymethylene, and a combination thereof.

10. A method according to claim 2, wherein the acidulant is selected from the group consisting of citric acid, carboxypolymethylene, and a combination thereof.

11. A method according to claim 4, wherein the second formulation has an aqueous carrier and a polymeric, water soluble acidulant, the acidulant having a molecular weight greater than approximately 100,000.

12. A method according to claim 11, wherein the acidulant is carboxypoly nethylene.

13. A method according to claim 12, wherein the carboxypolymethylene further acts as a thickener.

14. A method according to claim 12, wherein the gel pH is between approximately 3.0 and approximately 4.5.

15. A method for oxidizing tooth-staining chromogens to whiten teeth, the method comprising:

(a) providing a first formulation having sodium chlorite as a chlorine dioxide precursor, the first formulation being a liquid having a liquid pH greater than 7.0, and a second formulation having carboxypolymethylene acting as an acidulant capable of generating chlorine dioxide upon contact with the precursor, the second formulation being a gel having a gel pH of between approximately 3.0 and approximately 6.0;

(b) applying the first formulation to a tooth in a subject's mouth;

(c) putting the second formulation into a dental tray;

(d) inserting the dental tray containing the second formulation into the subject's mouth, so as to generate a chlorine dioxide film at an interface between the precursor and the acidulant proximate the tooth, wherein proximate to the film, a film pH is between approximately 3.0 and approximately 6.0; and

(e) removing the dental tray after the tooth has been exposed to chlorine dioxide generated proximate to the tooth for a time period of between approximately five minutes and approximately sixty minutes.

16. A method according to claim 15, wherein the carboxypolymethylene further acts as a thickener.

17. A method according to claim 16, wherein the liquid is aqueous.

18. A method according to claim 17, wherein the gel pH is between approximately 3.0 and approximately 4.5.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,944,528
DATED : August 31, 1999
INVENTOR(S) : R. Eric Montgomery

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8, line 18, change the words "carboxypoly nethylene" to one word "carboxypolymethylene"

Signed and Sealed this

Thirty-first Day of October, 2000

Attest:

Q. TODD DICKINSON

Attesting Officer

Director of Patents and Trademarks

TABLE 5

Tooth #	Gel	Light Source	Power Density (mW/cm2)	Filter	Test Duration	Initial Shade	Final Shade	Shade Change
HE101	Example 1	MH	250	505	3 × 20 min	A3.5	A1	7
HE102	Example 1	MH	250	505	3 × 20 min	B4	A2	8
HE103	Example 1	MH	175	505	3 × 20 min	A3	B1+	8
HE104	Example 1	MH	175	505	3 × 20 min	A4	B2	12
HE105	Example 1	MH	175	505	3 × 20 min	B3	B2	8
HE106	Example 1	MH	175	505	3 × 20 min	A3	B1+	8
HE107	Example 1	MH	175	505	3 × 20 min	A4	A2	10
HE108	Example 1	No light			3 × 20 min	A3.5	A3	3
HE109	Example 1	No light			3 × 20 min	A4	D3	5
HE110	Example 1	No light			3 × 20 min	A3.5	A3.5	0
HE111	Example 1	No light			3 × 20 min	A4	A3	6
HE112	Example 1	No light			3 × 20 min	A4	A3.5	3
HE113	None	MH	175	505	3 × 20 min	A3	A3	0
HE114	None	MH	175	505	3 × 20 min	A4	A4	0
HE115	None	MH	175	505	3 × 20 min	A3.5	A3	3
HE116	None	MH	175	505	3 × 20 min	B3	B3	0

EXAMPLE VI

A pulpal chamber of an endo-tooth in a cooperative and informed patient was wired using a thermal probe and thermo-conducting paste. Pulpal temperatures were measuring during an actual whitening procedure, in which the illumination was supplied using the currently available Union Broach Illuminator and the device described in the instant application used at the most preferred wavelengths of 400 to 505 nanometers. Measurements of the energy densities at the tooth surface showed comparable energy densities for each device (230 milliwatts/cm^2 for the Union Broach Illuminator and 200 milliwatts/cm^2 for the device described in the instant application, respectively). The results are shown below in Table 6.

Illumination using the device described in the instant application in the preferred wavelength range from about 400 to 505 nanometers raised pulpal chamber temperature less than did the Union Broach device. In this experiment, temperatures rose to a maximum by twenty minutes and were then stable. In contrast to the temperature rise seen with the Union Broach device, at no time did the temperature using the device disclosed in the instant application rise above the 5.5° C. which could result in thermally induced pulpitis if maintained for a significant period of time. The temperature changes seen are likely to be greater than those seen with vital teeth as endo-teeth have no blood supply to provide additional cooling.

	Temperature Rise (deg. C. from ambient)	
Time (min.)	Union Broach	BriteSmile 2000
5	4	2.9
10	8	4.5
15	9	5.3
20	9	4.2
25	9.5	4.5
30	9	4.3

Upon reading the subject application, various alternative constructions and embodiments will become obvious t those skilled in the art. These variations are to be considered within the scope and spirit of the subject invention. The subject invention is only to be limited by the claims which follow and their equivalents.

What is claimed:

1. A method for light-activated tooth whitening comprising the steps of:

applying a photosensitizing agent which absorbs actinic radiation when in contact with the surface of a tooth to one or more teeth;

applying an tooth-whitening composition containing a transparent carrier compound and a transparent oxidizing compound capable of facilitating tooth whitening on top of said photosensitizing agent; and

exposing said photosensitizing agent and said tooth-whitening composition to actinic light to activate said oxidizing compound.

2. A method as set forth in claim 1 wherein said photosensitizing agent absorbs light having a range of wavelengths from about 350 nanometers to about 700 nanometers and converts that energy into thermal or chemical energy.

3. A method as set forth in claim 2 wherein said photosensitizing agent absorbs light having a range of wavelengths from about 380 nanometers to about 500 nanometers.

4. A method as set forth in claim 1 wherein said photosensitizing agent is of molecular size, pH and surface charge to allow for effective penetration into the structure of the enamel and dentin.

5. A method as set forth in claim 1 wherein said photosensitizing agent is selected from a group consisting of nanometer sized semiconductor particles, benzophenone derivatives, benzotriazole derivatives, diketones, metal-ligand complexes, and phthalocyancin-metal complexes.

6. A method as set forth in claim 1 wherein said light source emits light having a range from about 350 nanometers to about 700 nanometers.

7. A method as set forth in claim 6 wherein said light source emits light having a range from about 380 nanometers to about 500 nanometers.

8. A method as set forth in claim 1, wherein the transparent oxidizing compound is selected from the group consisting of peroxides, peroxyacids and combinations thereof.

9. A method as set forth in claim 8, wherein the transparent oxidizing compound is a peroxide.

10. A method as set forth in claim 9, wherein the peroxide is hydrogen peroxide.

11. A method as set forth in claim 8, wherein the transparent oxidizing compound is a peroxyacid.

12. A method as set forth in claim 11, wherein the peroxyacid is peroxyacetic acid.

* * * * *

tooth surface is advantageous. By generating the peroxyacid (in this invention, peroxyacetic acid) on and within the tooth (thus in intimate contact with the stain-causing molecules themselves), superior tooth whitening results may be obtained. Although not wishing to be bound by any particular theory, it is believed that deeper penetration into the tooth structure by a first element (one of either a hydrogen peroxide precursor composition or a glyceryl triacetate composition) prior to contact with the second element will generate peroxyacetic acid (upon placement of the second remaining element) at the same site reached by the first element. In this manner, the depth at which tooth whitening occurs by the inventive compositions may be controlled. The in situ method described above has an additional advantage, in that the amount of peroxyacetic acid can be limited to that amount formed within the tooth structure itself (i.e. only where both of the required elements are present simultaneously). Accordingly, one aspect of the present invention involves the application of a composition or component of the composition onto the tooth surface and then allowing the composition or a first component of the composition to penetrate within the tooth structure itself. Peroxyacid is then allowed to generate within the tooth structure by application of an aqueous solution or a second component capable of reacting with the first component to generate a peroxyacid.

This in situ tooth whitening method may also be used with other peroxyacid precursors other than, and/or in addition to, glyceryl triacetate. Such peroxyacid precursors include all water-soluble or partially water-soluble compounds containing at least one acetyl group functionality, including, but not limited to acetylated amino acids (such as acetyl cysteine, acetyl glycine, etc) and acetylated polymers. Due to the desired penetration into the tooth structure in order to reach deeper stains, low molecular weight (<1000) acetyl group-containing molecules are preferred.

EXAMPLE VII

A single-component toothpaste containing a very low level of water was prepared that contained glyceryl triacetate, together with sodium percarbonate as a hydrogen peroxide precursor.

Ingredient	Percent (w/w)
Polyethylene glycol 400	34.76
Polyethylene glycol 3350	1.00
Water	1.80
Glyceryl triacetate	2.00
Sodium percarbonate	5.00
Sodium bicarbonate	50.00
Hydrated silica	1.60
Sodium lauryl sulfate	0.60
Sodium methyl cocoyl taurate	0.60
Sodium fluoride	0.24
Sodium saccharin	1.20
Flavor	1.20
TOTAL	100.00

The above composition was manufactured in a manner similar to that described in the Examples above and packaged in plastic tubes. Upon extruding a small amount of the toothpaste and combining it with water at a ratio of 1 part by weight toothpaste to 1 part by weight water, an immediate odor of peroxyacetic acid was evident.

EXAMPLE VIII

Chewing gum containing a thin slurry coating of sodium percarbonate and glyceryl triacetate in vegetable oil was prepared. A slurry of sodium percarbonate was first made by manually stirring approximately 2.0 percent by weight of sodium percarbonate powder (Solvay FB 100) into a mixture of 20 parts highly refined avocado oil (Super Refined Avocado Oil, Croda, Inc) and 1 part glyceryl triacetate (by volume). A portion of the resulting slurry (approximately 0.30 grams) was brushed onto the surface of a stick of a commercially available chewing gum (Extra, Wm. Wrigley & Son, Chicago, Ill.) and allowed to absorb overnight.

When manually kneaded in the presence of surface moisture provided by dabbing the gum bolus onto a wet surface, a slight odor of peroxyacetic acid was detected after about 30 seconds. It is expected that a similar result would be obtained upon chewing a stick of gum similarly prepared, thus providing peroxyacetic acid to the oral cavity, including the surface of the teeth.

It is anticipated that other modes of applying, blending, combining, and otherwise mixing together the components of chewing gum with the inventive components, namely a hydrogen peroxide precursor and glyceryl triacetate will result in a solid, chewable object capable of generating peroxyacetic acid upon contact with moisture from saliva.

It is to be understood that the embodiments of the present invention which have been described are merely illustrative of some of the applications of the principles of the present invention. Numerous modifications may be made by those skilled in the art based upon the teachings presented herein without departing from the true spirit and scope of the invention.

What is claimed is:

1. A method for whitening teeth comprising:

forming a composition having a pH in excess of about 5.2 by combining a hydrogen peroxide precursor in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the oral care composition, glyceryl triacetate in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the oral care composition, and water so as to generate peroxyacetic acid; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

2. A method for whitening teeth comprising:

providing separately glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth;

forming a composition having a pH in excess of about 5.2 including a mixture between the glyceryl triacetate and the hydrogen peroxide releasing compound with the glyceryl triacetate being in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the composition and with the hydrogen peroxide releasing compound being in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the composition; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

* * * * *

mide polymers, poly (vinylpyrrolidone), and mixed partial salts of poly(methyl vinyl ether-co-maleic and increase inviscosity and cohesion as a result of the absorption of water from the growth medium. Zone of inhibition studies were carried out as previously described in Example I. After 48 hours, the triclosan-containing denture adhesive above exhibited a zone of inhibition of approximately 3–4 mm, while a commercial available denture adhesive did not exhibit a zone of inhibition. In fact, the surface of the commercial denture adhevise was colonized by *S. mutans* after the 48-hour test period. The addition of triclosan to the denture adhesive formulation above resulted in a composition capable of inhibiting microorganisms in the volume surrounding the swollen or cured adhesive mass.

It is to be understood that the embodiments of the present invention which have been described are merely illustrative of some of the applications of the principles of the invention. Numerous modifications may be made by those skilled in the art based upon the teachings presented herein without departing from the true spirit and scope of the invention.

What is claimed is:

1. An artificial fingernail composition, comprising: a polymerizable system and a water-insoluble anti-microbial agent inert to the polymerizable system, wherein said composition is cured to produce an artificial fingernail.

2. An artificial fingernail comprising a cured polymerization system and a water-insoluble anti-microbial agent inert to the polymerization system, wherein said anti-microbial agent provides a zone of inhibition of growth of bacteria surrounding said artificial fingernail.

3. The artificial fingernail of claim 1 wherein said water insoluble antimicrobial agent is selected from the group consisting of halogenated diphenyl ethers, halogenated salicylanilides, benzoic esters, halogenated carbanalides and phenolic compounds.

4. The artificial fingernail of claim 1 wherein said water insoluble antimicrobial agent is triclosan.

5. The artificial fingernail of claim 4 wherein said triclosan is present in an amount of 0.3% by weight of non-volatile solids.

6. The artificial fingernail of claim 4 wherein said triclosan is present in an amount of 1.0% by weight of non-volatile solids.

* * * * *

the top surface, were stained in a manner to duplicate the tooth staining observed in vivo by humans (alternately exposed to air and a staining broth at 37 degrees C. containing typticase soy broth, tea, coffee, mucin, $FeCl_3$, and *Sarcina lutea*, for a period of about four days). Each stained bovine incisor was numbered and measured for degree of staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer (3 mm aperture, 8 exposure averaging, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes, whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below as ΔE. Absolute color change is defined as the square root of the sum of the squares of all color components (L, a, and b).

$$\sqrt{(\Delta L)^2+(\Delta a)^2+(\Delta b)^2}=\Delta E$$

TABLE 4

Tooth #	Product/ Example	pH (neat)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5 (2) to 6.0 (3) results in an increased ΔE from 4.29 to 6.27.

The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating agent. There was an observed improvement in ΔE in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

Opalescence is a commercial product which has been pH adjusted to pH 6.5 before use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that the pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

EXAMPLE 5

In vivo Demonstration of Tooth Bleaching

Six volunteers aged 25 to 43 were separated into two groups of two and custom dental trays were fashioned for each participant in the study.

One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

Patient #	Product/ Example	Treatment Time (minutes)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65
4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

The average ΔE for the Example 1B group was 7.32, whereas the average ΔE for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

I claim:

1. A method for bleaching the teeth of a subject comprising:

providing a multi-chamber vessel, the vessel including a first chamber having a first formulation including a hydrogen peroxide precursor compound selected from the group consisting of an alkali metal percarbonate, carbamide peroxide, calcium peroxide, and an alkali metal perborate, a thickener, a carrier and a calcium chelating agent wherein the first formulation is substantially free of an alkaline pH adjusting agent and is substantially free of water and

a second chamber having a second formulation including an alkaline pH adjusting agent selected from the group consisting of alkali metal hydroxides, ammonium

hydroxide, alkali metal carbonates, TRIS, and triethanolamine, a carrier and a thickener wherein the second formulation is substantially free of the hydrogen peroxide precursor compound;

applying pressure to the multi-chamber vessel, so as to force the first and second formulations through a mixing baffle to form a mixture which then emerges from a single exit, the mixture being a thickened, aqueous, hydrogen peroxide containing composition and being bicarbonate free and abrasive free and having a pH of between approximately 6 and approximately 10; and

contacting the mixture to the teeth of the subject for less than one hour.

2. A method according, to claim 1, wherein the pH adjusting agent is ammonium hydroxide and the calcium chelating agent is 1-hydroxyethylidene-1,1-diphosphonic acid.

3. A method according to claim 1, wherein the calcium chelating agent is selected from the group consisting of EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates, alkali metal polyphosphates, diphosphonic acids, and combinations thereof.

4. A method according to claim 1, wherein the mixture has a water content of more than about 70% by weight of the mixture.

5. A method according to claim 1 further comprising:

maintaining the mixture upon the teeth for an extended time period, the time period being between approximately 10 minutes and approximately 30 minutes.

6. A method for bleaching the teeth of a subject comprising:

providing a multi-chamber vessel, the vessel including a first chamber having a first formulation including hydrogen peroxide, a thickener, an aqueous carrier and a calcium chelating agent wherein the first formulation is substantially free of an alkaline pH adjusting agent and

a second chamber having a second formulation including an alkaline pH adjusting agent selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine, a carrier and a thickener wherein the second formulation is substantially free of hydrogen peroxide;

applying pressure to the multi-chamber vessel, so as to force the first and second formulations through a mixing baffle to form a mixture which then emerges from a single exit, the mixture being a thickened, aqueous, hydrogen peroxide containing composition and being bicarbonate free and abrasive free and having a pH of between approximately 6 and approximately 10; and

contacting the mixture to the teeth of the subject for less than one hour.

7. A method according to claim 6 wherein the pH adjusting agent is ammonium hydroxide and the calcium chelating agent is 1-hydroxyethylidene-1,1 -diphosphonic acid.

8. A method according to claim 6, wherein the calcium chelating agent is selected from the group consisting of EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates, alkali metal polyphosphates, diphosphonic acids, and combinations thereof.

9. A method according to claim 1, wherein the mixture has a water content of more than about 70% by weight of the mixture.

10. A method according to claim 1 further comprising:

maintaining the mixture upon the teeth for an extended time period, the time period being between approximately 10 minutes and approximately 30 minutes.

* * * * *

the top surface, were stained in a manner to duplicate the tooth staining observed in vivo by humans (alternately exposed to air and a staining broth at 37 degrees C. containing typticase soy broth, tea, coffee, mucin, $FeCl_3$, and *Sarcina lutea*, for a period of about four days). Each stained bovine incisor was numbered and measured for degree of staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer (3 mm aperture, 8 exposure averaging, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes, whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below as ΔE. Absolute color change is defined as the square root of the sum of the squares of all color components (L,a, and b).

$$\sqrt{[(\Delta L)^2+(\Delta a)^2+(\Delta b)^2]}=\Delta E$$

TABLE 4

Tooth #	Product/ Example	pH (neat)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5 (2) to 6.0 (3) results in an increased ΔE from 4.29 to 6.27.

The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating agent. There was an observed improvement in ΔE in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

Opalescence is a commercial product which has been pH adjusted to pH 6.5 before use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that the pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

Example 5

In Vivo Demonstration of Tooth Bleaching

Six volunteers aged 25 to 43 were separated into two groups of two and custom dental trays were fashioned for each participant in the study.

One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

Patient #	Product/ Example	Treatment Time (minutes)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65
4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

The average ΔE for the Example IB group was 7.32, whereas the average ΔE for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

I claim:

1. A single exit dual compartment squeeze tube with a static mixer, whose compartments are adapted to keep apart two formulations and whose two compartments respectively include:

a first formulation comprising a hydrogen peroxide precursor compound selected from the group consisting f an alkali metal percarbonate, carbamide peroxide, cal-

cium peroxide, and an alkali metal perborate, a thickener, a carrier and a calcium chelating agent wherein the first formulation is substantially free of an alkaline pH adjusting agent and is substantially free of water; and

a second formulation comprising an alkaline pH-adjusting agent selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine, a carrier and a thickener wherein the second formulation is substantially tree of the hydrogen peroxide precursor compound; whereby squeezing the tube forces material from each compartment through the static mixer to form a thickened, aqueous, substantially bicarbonate free, and substantially abrasive free hydrogen peroxide containing mixture before emerging from the single exit in the tube, wherein the mixture has a range of pH between approximately 6 and approximately 10.

2. The single exit dual compartment squeeze tube according to claim 1, wherein the hydrogen peroxide precursor compound is a percarbonate salt.

3. The single exit dual compartment squeeze tube according to claim 2, wherein the percarbonate salt is selected from the group consisting of sodium and potassium percarbonate.

4. The single exit dual compartment squeeze tube according to claim 1, wherein the calcium chelating agent is selected from the group consisting of EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates and alkali metal polyphosphates.

5. The single exit dual compartment squeeze tube according to claim 4, wherein the calcium chelating agent further acts as a stabilizing agent for the hydrogen peroxide precursor compound.

6. The single exit dual compartment squeeze tube according to claim 8, wherein the calcium chelating agent is 1-hydroxyethylidene-1,1-diphosphonic acid.

7. The single exit dual compartment squeeze tube according to claim 1, wherein the composition is capable of a detectable tooth-bleaching effect within 30 minutes.

8. The single exit dual compartment squeeze tube according to claim 1, the first formulation comprising:

less than about 0.5% by weight, based on the weight of the mixture, of the calcium chelating agent.

9. The single exit dual compartment squeeze tube according to claims 8, wherein the first formulation has less than about 0.1% by weight, based on the weight of the composition, of the calcium chelating agent.

10. The single exit dual compartment squeeze tube according to claim 1, wherein the second formulation is aqueous.

11. The single exit dual compartment squeeze tube according to claim 1, wherein the thickening agent is a high molecular weight cross linked polyacrylic acid.

12. A single exit dual compartment squeeze tube with a static mixer, whose compartments are adapted to keep apart two formulations and whose two compartments respectively include:

a first formulation comprising hydrogen peroxide, a thickener, an aqueous carrier and a chelating agent wherein the first formulation is substantially free of an alkaline pH adjusting agent; and

a second formulation comprising an alkaline pH-adjusting agent selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine, a carrier and a thickener wherein the second formulation is substantially free of the hydrogen peroxide; whereby squeezing the tube forces material from each compartment through the static mixer to form a thickened, aqueous, substantially bicarbonate free, and substantially abrasive free hydrogen peroxide containing mixture before emerging from the single exit in the tube, wherein the mixture has a range of pH between approximately 6 and approximately 10.

13. The single exit dual compartment squeeze tube according to claim 12, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the mixture.

14. The single exit dual compartment squeeze tube according to claim 12, wherein the calcium chelating agent is selected from the group consisting of EDTA and its salts, citric acid and its salts, gluconic acid and its salts, alkali metal pyrophosphates and alkali metal polyphosphates.

15. The single exit dual compartment squeeze tube according to claim 12, wherein the calcium chelating agent is 1-hydroxyethylidene-1,1-diphosphonic acid.

16. The single exit dual compartment squeeze tube according to claim 1, wherein the mixture is capable of a detectable tooth-bleaching effect within 30 minutes.

17. The single exit dual compartment squeeze tube according to claim 12, the first formulation comprising:

less than about 0.5% by weight, based on the weight of the mixture, of the calcium chelating agent.

18. The single exit dual compartment squeeze tube according to claim 12, wherein the first formulation has less than about 0.1% by weight, based on the weight of the composition, of the calcium chelating agent.

19. The single exit dual compartment squeeze tube according to claim 12, wherein the concentration of hydrogen peroxide in the mixture is in a range between approximately 5% and approximately 12% by weight of the mixture.

20. The single exit dual compartment squeeze tube according to claim 12, wherein the thickening agent is a high molecular weight cross linked polyacrylic acid.

* * * * *

the top surface, were stained in a manner to duplicate the tooth staining observed in vivo by humans (alternately exposed to air and a staining broth at 37 degrees C. containing typticase soy broth, tea, coffee, mucin, $FeCl_3$, and *Sarcina lutea*, for a period of about four days). Each stained bovine incisor was numbered and measured for degree of staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer (3 mm aperture, 8 exposure average, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes, whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below as ΔE. Absolute color change is defined as the square root of the sum of the squares of all color components (L, a, and b).

$$\sqrt{[(\Delta L)^2+(\Delta a)^2+(\Delta b)^2]}=\Delta E$$

TABLE 4

Tooth #	Product/ Example	pH (neat)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5 (2) to 6.0 (3) results in an increased ΔE from 4.29 to 6.27.

The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating agent. There was an observed improvement in ΔE in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

Opalescence is a commercial product which has been pH adjusted to pH 6.5 before use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that the pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

EXAMPLE 5

In vivo Demonstration of Tooth Bleaching

Six volunteers aged 25 to 43 were separated into two groups of two and custom dental trays were fashioned for each participant in the study.

One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

Patient #	Product/ Example	Treatment Time (minutes)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65
4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

The average ΔE for the Example 1B group was 7.32, whereas the average ΔE for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

I claim:

1. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising

hydrogen peroxide in an effective tooth whitening amount,

an aqueous matrix comprising

a calcium chelating agent,

a thickening agent, and

an alkaline pH adjusting agent,

wherein the mixture has a pH within a range of between approximately 6.0 and approximately 10.0 and wherein the mixture is packaged as a single component system.

2. A composition according to claim 1, wherein the water content is at least 75% by weight, based on the weight of the composition.

3. A composition according to claim 1, wherein the mixture has a pH within a range of between approximately 7.0 and approximately 10.0.

4. A composition according to claim 1, wherein the thickening agent is a high molecular weight crosslinked polyacrylic acid.

5. A composition according to claim 1, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the composition.

6. A composition according to claim 1, wherein the matrix also has a stabilizing agent selected from the group consisting of sodium stannate trihydrate, 1-Hydroxyethylidene-1, 1-diphosphonic acid, and combinations thereof.

7. A composition according to claim 6, wherein the stabilizing agent may also act as a calcium chelating agent.

8. A composition according to claim 6, wherein the aqueous matrix has a water content of at least 70% by weight, based on the weight of the composition.

9. A composition according to claim 6, wherein the matrix is sufficiently pure in order to avoid peroxide destabilization by metal ion contaminants, so as to permit packaging as a one-component system.

10. A composition according to claim 6, wherein the mixture has a pH within a range of between approximately 7.0 and approximately 10.0.

11. A composition according to claim 6, wherein the thickening agent is a high molecular weight crosslinked polyacrylic acid.

12. A composition according to claim 6, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the composition.

13. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising:

hydrogen peroxide,

an aqueous matrix comprising

a high molecular weight crosslinked polyacrylic acid in an amount between approximately 2.0% and approximately 5.0% by weight, based on the weight of the mixture,

an alkaline pH adjusting agent, and

sodium stannate trihydrate, 1-Hydroxyethylidene-1,1-diphosphonic acid, and combinations thereof, in an amount between approximately 0.02% and approximately 0.5% by weight, based on the weight of the mixture,

wherein the mixture has a pH within a range of between approximately 6.0 and approximately 10.0 and wherein the mixture is packaged as a single component system.

14. A composition according to claim 13, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the composition.

15. A composition according to claim 13, wherein the mixture has a pH within a range of between approximately 7.0 and approximately 10.0.

16. A composition according to claim 13, wherein the matrix also has

a concentration of a calcium chelating agent of between approximately 0.02% and approximately 0.4% by weight, based on the weight of the composition.

17. A composition according to claim 13, wherein the stabilizing agent may also act as a calcium chelating agent.

18. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising

hydrogen peroxide in an effective tooth whitening amount

a thickening agent,

water,

a calcium chelating agent, and

an alkalizing agent,

wherein the tooth bleaching mixture has a pH within a range of between approximately 7.0 and approximately 10.0 and wherein the tooth bleaching mixture is a single component system.

19. The tooth bleaching mixture of claim 18 wherein the tooth bleaching mixture has a pH within a range of between approximately 7.5 and approximately 9.0.

20. The tooth bleaching mixture of claim 18 wherein the tooth bleaching mixture has a pH of approximately 8.

* * * * *

TABLE 5

Tooth #	Gel	Light Source	Power Density (mW/cm²)	Filter	Test Duration	Initial Shade	Final Shade	Shade Change
HE101	Example 1	MH	250	505	3 × 20 min	A3.5	A1	7
HE102	Example 1	MH	250	505	3 × 20 min	B4	A2	8
HE103	Example 1	MH	175	505	3 × 20 min	A3	B1+	8
HE104	Example 1	MH	175	505	3 × 20 min	A4	B2	12
HE105	Example 1	MH	175	505	3 × 20 min	B3	B2	8
HE106	Example 1	MH	175	505	3 × 20 min	A3	B1+	8
HE107	Example 1	MH	175	505	3 × 20 min	A4	A2	10
HE108	Example 1	No light			3 × 20 min	A3.5	A3	3
HE109	Example 1	No light			3 × 20 min	A4	D3	5
HE110	Example 1	No light			3 × 20 min	A3.5	A3.5	0
HE111	Example 1	No light			3 × 20 min	A4	A3	6
HE112	Example 1	No light			3 × 20 min	A4	A3.5	3
HE113	None	MH	175	505	3 × 20 min	A3	A3	0
HE114	None	MH	175	505	3 × 20 min	A4	A4	0
HE115	None	MH	175	505	3 × 20 min	A3.5	A3	3
HE116	None	MH	175	505	3 × 20 min	B3	B3	0

EXAMPLE VI

A pulpal chamber of an endo-tooth in a cooperative and informed patient was wired using a thermal probe and thermo-conducting paste. Pulpal temperatures were measuring during an actual whitening procedure, in which the illumination was supplied using the currently available Union Broach Illuminator and the device described in the instant application used at the most preferred wavelengths of 400 to 505 nanometers. Measurements of the energy densities at the tooth surface showed comparable energy densities for each device (230 milliwatts/cm² for the Union Broach Illuminator and 200 milliwatts/cm² for the device described in the instant application, respectively). The results are shown below in Table 6.

Illumination using the device described in the instant application in the preferred wavelength range from about 400 to 505 nanometers raised pulpal chamber temperature less than did the Union Broach device. In this experiment, temperatures rose to a maximum by twenty minutes and were then stable. In contrast to the temperature rise seen with the Union Broach device, at no time did the temperature using the device disclosed in the instant application rise above the 5.5° C. which could result in thermally induced pulpitis if maintained for a significant period of time. The temperature changes seen are likely to be greater than those seen with vital teeth as endo-teeth have no blood supply to provide additional cooling.

Time	Temperature Rise (deg. C. from ambient)	
(min.)	Union Broach	BriteSmile 2000
5	4	2.9
10	8	4.5
15	9	5.3
20	9	4.2
25	9.5	4.5
30	9	4.3

Upon reading the subject application, various alternative constructions and embodiments will become obvious t those skilled in the art. These variations are to be considered within the scope and spirit of the subject invention. The subject invention is only to be limited by the claims which follow and their equivalents.

What is claimed:

1. A method for light-activated tooth whitening comprising the steps of:

applying a tooth-whitening composition to one or more teeth, wherein the tooth whitening composition comprises a transparent carrier compound, a transparent oxidizing compound, a photosensitizer precursor which when in contact with the surface of a stained tooth becomes a photosensitizing agent, wherein the photosensitizing agent when exposed to actinic light activates the oxidizing compound to facilitate tooth whitening at the surface of the teeth, and

exposing the tooth-whitening composition to actinic light to activate the oxidizing compound.

2. A method according to claim 1, wherein the photosensitizer precursor is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DETPA), nitrilotriacetic acid (NTA), 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra(methylenephosphonic acid) and diethylenetriamine penta(methylenephosphonic acid).

3. A method according to claim 2, wherein the photosensitizer precursor is 1-hydroxyethylidene-1,1-diphosphonic acid.

4. A method according to claim 1, wherein the actinic light has a wavelength in the range from about 380 nanometers to about 700 nanometers.

5. A method according to claim 1, wherein the actinic light has a wavelength in the range from about 380 nanometers to about 500 nanometers.

6. A method according to claim 1, wherein the transparent oxidizing compound is selected from the group consisting of peroxides, peroxyacids and combinations thereof.

7. A method according to claim 6, wherein the transparent oxidizing compound is a peroxide.

8. A method according to claim 7, wherein the peroxide is hydrogen peroxide.

9. A method according to claim 6, wherein the transparent oxidizing compound is a peroxyacid.

10. A method according to claim 9, wherein the peroxyacid is peroxyacetic acid.

11. A method of light-activated tooth whitening comprising the steps of:

applying a tooth-whitening composition to one or more teeth, wherein the tooth whitening composition comprises a transparent oxidizing compound, a transparent

carrier, and a photosensitizer precursor which when chelated to endogenous metal ions present at the tooth surface becomes a photosensitizing agent, wherein the photosensitizing agent when exposed to actinic light activates the oxidizing compound to facilitate tooth whitening at the surface of the teeth, and

exposing the tooth-whitening composition to actinic light to activate the oxidizing compound.

12. A method according to claim 11, wherein the photosensitizer precursor is a metal ion chelator.

13. A method according to claim 11, wherein the photosensitizer precursor is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DETPA), nitrilotriacetic acid (NTA), 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra(methylenephosphonic acid) and diethylenetriamine penta(methylenephosphonic acid).

14. A method according to claim 13, wherein the photosensitizer precursor is 1-hydroxyethylidene-1,1-diphosphonic acid.

15. A method according to claim 11, wherein the transparent oxidizing compound is selected from the group consisting of peroxides, peroxyacids and combinations thereof.

16. A method according to claim 15, wherein the transparent oxidizing compound is a peroxide.

17. A method according to claim 16, wherein the peroxide is hydrogen peroxide.

18. A method according to claim 11, wherein the transparent oxidizing compound is a peroxyacid.

19. A method according to claim 18, wherein the peroxyacid is peroxyacetic acid.

20. A method according to claim 11, wherein the endogenous metal ions are present in the saliva and the interstitial fluid of enamel and dentin.

21. A method according to claim 11, wherein the endogenous metal ions are transition metal ions.

22. A method according to claim 11, wherein the endogenous metal ions are selected from the group consisting of iron, manganese and copper.

23. A method according to claim 22, wherein the endogenous metal ions are iron.

24. A method according to claim 11, wherein the actinic light has a wavelength in the range from about 380 nanometers to about 700 nanometers.

25. A method according to claim 11, wherein the actinic light has a wavelength in the range from about 380 nanometers to about 500 nanometers.

26. A method for light-activated tooth whitening comprising the steps of:

applying a tooth-whitening composition to one or more teeth, wherein the tooth whitening composition comprises a transparent oxidizing compound, a transparent carrier and a photosensitizer precursor which chelates endogenous metal ions present at the tooth surface and becomes a photosensitizing agent upon chelating the endogenous metal ions, and wherein the photosensitizing agent, when exposed to actinic light, activates the oxidizing compound to facilitate tooth whitening at the surface of the teeth, and

exposing the tooth-whitening composition to actinic light delivered from a position outside of a patient's mouth to activate the oxidizing compound.

27. A method according to claim 26, wherein the photosensitizer precursor is selected from the group consisting of ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DETPA), nitrilotriacetic acid (NTA), 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra()methylenephosphonic acid) and diethylenetriamine penta(methylenephosphonic acid).

28. A method according to claim 27, wherein the photosensitizer precursor is 1-hydroxyethylidene-1,1-diphosphonic acid.

29. A method according to claim 26, wherein the transparent oxidizing compound is selected from the group consisting of peroxides, peroxyacids and combinations thereof.

30. A method according to claim 29, wherein the transparent oxidizing compound is a peroxide.

31. A method according to claim 30, wherein the peroxide is hydrogen peroxide.

32. A method according to claim 29, wherein the transparent oxidizing compound is a peroxyacid.

33. A method according to claim 32, wherein the peroxyacid is peroxyacetic acid.

34. A method according to claim 26, wherein the endogenous metal ions are present in the saliva and the interstitial fluid of enamel and dentin.

35. A method according to claim 26, wherein the endogenous metal ions are transition metal ions.

36. A method according to claim 26, wherein the endogenous metal ions are selected from the group consisting of iron, manganese, copper and combinations thereof.

37. A method according to claim 36, wherein the endogenous metal ions are iron.

38. A method according to claim 26, wherein the actinic light has a wavelength in the range from about 380 nanometers to about 700 nanometers.

39. A method according to claim 26, wherein the actinic light has a wavelength in the range from about 380 nanometers to about 500 nanometers.

40. A method of light-activated tooth whitening comprising the steps of:

contacting one or more tooth surfaces of a patient with an oxidizing composition comprising an oxidizing compound and a photosensitizer precursor, and

applying actinic radiation to the patient's one or more tooth surfaces.

41. A method according to claim 40, wherein the actinic radiation is transmitted through the oxidizing composition.

42. A method according to claim 40, wherein the actinic radiation is applied to the one or more tooth surfaces at from about 10 to about 200 milliWatt/cm^2.

43. A method of light-activated tooth whitening comprising the steps of:

contacting one or more tooth surfaces of a patient with an oxidizing composition comprising an oxidizing compound and a photosensitizer precursor, wherein the oxidizing composition is sufficiently transparent to actinic radiation such that about 10 to about 200 milliWatt/cm^2 of light can be applied to the one or more tooth surfaces, and

applying actinic radiation to the patient's one or more tooth surfaces.

* * * * *

of the test dentifrice to clean extrinsic stained pellicle from teeth. The data were calculated and defined as follows:

(1) Stained Pellicle Removed=Baseline stain reading minus the reading after treatment.

(2) Total Stained Pellicle Available=Stain reading minus the reading following treatment and pumicing.

(3) % Total Stained Pellicle Removed="Stained Pellicle Removed" divided by the "Total Stained Pellicle Available".

The overall change in stained pellicle was calculated using the CIELAB equation

$$\Delta E=[(\Delta L^*)^2+(\Delta a^*)^2+(\Delta b^*)^2]^{1/2}$$

The individual components of the L*a*b* factors were also analyzed separately to determine the specific changes in lightness, redness, and yellowness, respectively.

Statistical significance of data for each category was determined by analysis of variance, and intergroup comparisons were made by means of the Studentized Newman-Keuls (SNK) range test. Data were tabulated using a PC and spreadsheet program (Lotus 1-2-3, Version 2.01, 1986, Lotus Development Corp., Cambridge, Mass.). Summary print files were then loaded into a VAX 8530 mainframe computer and analyzed by means of a conventional statistics program (SAS, SAS Institute Inc., Cary, N.C.). All SNK comparisons were made using a 2-tail test.

TABLE 2

Effectiveness of the inventive dentifrice versus a placebo dentifrice

Dentifrice	ΔE	% Reduction of Stain
A	12.43 +/- 2.52	48%
B	16.23 +/- 3.26	66%

The study demonstrated an improvement in stain removal gained from the inclusion of the destabilizing agent sodium tripolyphosphate and the complexing agent poly(vinyl pyrrolidone) in dentifrice B, when compared against to the same dentifrice A without the destabilizing and complexing agents.

EXAMPLE III

Tooth stain removal studies were also conducted to determine the ability of some of the dentifrice compositions of the present invention, and in particular, dentifrice composition B, in removing tooth stains versus some non-peroxide, commercially available tooth whitening dentifrice compositions.

The procedure of Example II was repeated with each of commercial dentifrice compositions A, B, and C. Commercial dentifrices A (CD-A) and B (CD-B) claim to have a high level of stain removing capability due to the inclusion of greater than 4% w/w sodium tripolyphosphate in the formulations. Commercial dentifrice C (CD-C) is a popular whitening dentifrice having citric acid, hydrated alumina, and papain (a proteolytic enzyme) as the stain-removing components. The abrasivity of the commercial dentifrices versus that of the dentifrice B is as follows:

CD-A=CD-B=Inventive Dentifrice B>CD-C

TABLE 3

Effectiveness of inventive dentifrice versus commercial dentifrices

Dentifrice	ΔE	% Reduction of Stain
Inventive Dentifrice B	16.23 +/- 3.26	66%
Commercial Dentifrice A	14.59 +/- 3.78	54%
Commercial Dentifrice B	10.66 +/- 2.50	45%
Commercial Dentifrice C	7.49 +/- 1.71	31%

Dentifrice B, formulated in accordance with an embodiment of the present invention, performed very well when compared to commercial dentifrice compositions utilizing a variety of different technologies for removing or eliminating tooth stains. Dentifrice B, despite having a lower level of destabilizing agent, sodium tripolyphosphate (e.g., 3 percent by weight) (see Table 1) than commercial dentifrices CD-A and CD-B (e.g., more than 4 percent by weight), performed substantially better in reducing tooth stains. In addition, dentifrice B reduces tooth significantly better than commercial dentifrice CD-C.

What is claimed is:

1. A dentifrice for removing tooth stain caused by an association of a chromogen with a layer of proteinaceous acquired pellicle on a tooth within an oral cavity, the dentifrice comprising:

about 2% to about 3% sodium tripolyphosphate by weight, to disassociate the chromogen from the layer of proteinaceous acquired pellicle; and

about 1% to about 2% polyvinyl pyrrolidone, having affinity to the disassociated chromogen to prevent reassociation of the chromogen with the layer of proteinaceous acquired pellicle.

2. A dentifrice according to claim 1 further including a detergent, wherein the detergent is selected from the group consisting of sodium lauryl sulfate, sodium methyl cocoyl taurate, and combinations thereof, the detergent having a concentration from about 0.6% to less that 5% by weight.

3. A dentifrice according to claim 1 further providing an oral pH level that is between approximately 7.0 and approximately 10.5.

4. A dentifrice according to claim 1 further being provided in a carrier which provides sufficient oral contact time to permit disassociation of the chromogen from the layer of proteinaceous acquired pellicle and to allow association of the chromogen with the polyvinyl pyrrolidone.

5. A dentifrice for removing tooth stain caused by an association of a chromogenic phenolic compound with a layer of proteinaceous acquired pellicle on a tooth within an oral cavity, the dentifrice comprising:

about 2% to about 3% w/w of sodium tripolyphosphate; and

about 1% to about 2% polyvinylpyrrolidone;

wherein the dentifrice provides an oral pH level between approximately 7.0 and approximately 10.5.

6. A dentifrice according to claim 5, the polyvinyl pyrrolidone having a K-value, the K-value being from about 25 to no greater than about 30.

7. A dentifrice according to claim 5, further including a detergent, wherein the detergent is selected from the group consisting of sodium lauryl sulfate, sodium methyl cocoyl taurate, and combinations thereof, the detergent having a concentration of from about 0.6% to less than 5% by weight.

8. A dentifrice according to claim 5 further being provided in a carrier which provides sufficient oral contact time to permit disassociation of the chromogen from the layer of proteinaceous acquired pellicle and to allow association of the chromogen with the polyvinyl pyrrolidone.

* * * * *

The results for all treated incisors are recorded in Table 1 below.

TABLE 1

Bovine Incisor		Initial Color			Final Color			
#	Treatment	L	a	b	L	a	b	ΔE
1	CDP only	45.38	3.68	10.42	47.11	3.21	10.09	1.82
2	ACD only	54.50	-1.80	0.90	56.10	-1.90	1.40	1.68
3	CDP/ACD	42.78	3.60	11.30	48.57	1.85	10.03	6.16
4	CDP/ACD	38.27	5.31	11.08	46.51	4.61	13.91	8.55
5	CDP/ACD	35.62	4.46	9.48	38.94	3.65	9.60	3.42
6	CDP/ACD	40.91	3.94	11.08	44.30	3.07	10.22	3.69
7	CDP/ACD	43.55	3.51	10.09	48.92	2.02	9.54	5.83

This table demonstrates that the inventive compositions, when applied as described above, are effective in removing tooth stains in an vitro stained bovine enamel model. The observed-tooth-whitening-effect-is-much greater, when the CDP and ADP portions are both applied, than when either just the CDP Portion or the ACD Portion is applied.

What is claimed is:

1. A composition comprising:

a first formulation comprising an alkali metal chlorite contacting a tooth stained with tooth-staining chromogens; and

a second formulation comprising an acidulant contacting the first formulation in a manner to form an interface between the first formulation and the second formulation, the interface further characterized by the presence of chlorine dioxide in an amount effective to oxidize tooth-staining chromogens such that the tooth is whitened.

2. The composition according to claim 1, wherein the acidulant is selected from the group consisting of citric acid, carboxypolymethylene, and a combination thereof.

3. The composition according to claim 1, wherein the alkali metal chlorite is sodium chlorite.

4. The composition according to claim 3, wherein the sodium chlorite has a concentration of no more than approximately 5000 parts per million based upon weight of the first formulation.

5. The composition according to claim 1, wherein the acidulant is carboxypolymethylene.

6. A method for oxidizing tooth-staining chromogens to whiten a tooth, the method comprising:

providing a first formulation having a pH greater than about 7 and a second formulation capable of generating chlorine dioxide upon contact with the first formulation, the second formulation having a pH from about 3 to about 6;

applying the first formulation to the tooth stained with tooth-staining chromogens;

applying the second formulation to the first formulation in a manner to establish an interface between the first and the second formulations;

generating chlorine dioxide at the interface in an amount effective to whiten the tooth; and

exposing the tooth to the chlorine dioxide for a time period of between approximately five minutes and approximately sixty minutes.

7. The composition according to claim 1, wherein the acidulant is citric acid.

8. The composition according to claim 7, wherein the citric acid has a concentration of no more than approximately 2 percent based upon weight of the second formulation.

9. The composition according to claim 5, carboxypolymethylene having a molecular weight greater than about 100,000.

10. The composition according to claim 1, the first formulation having a pH from about 7.5 to about 9.0, and the second formulation having a pH from about 3.0 to about 6.0

11. The composition according to claim 1, the second formulation having a pH from about 3.0 to about 4.5.

12. The composition according to claim 1, the interface having a pH from about 3.0 to about 6.0.

13. The composition according to claim 1, the interface having a pH from about 3.0 to about 4.5.

14. The composition according to claim 1, wherein the first formulation is a liquid and the second formulation is a gel.

15. The method according to claim 6, the second formulation comprising an acidulant.

16. The method according to claim 15, wherein the acidulant is selected from the group consisting of citric acid, carboxypolymethylene, and a combination thereof.

17. The method according to claim 15, wherein the acidulant is citric acid.

18. The method according to claim 17, wherein the citric acid has a concentration of no more than approximately 2 percent based upon weight of the second formulation.

19. The method according to claim 15, wherein the acidulant is carboxypolymethylene.

20. The method according to claim 19, the carboxypolymethylene having a molecular weight greater than about 100,000.

21. The method according to claim 6, first formulation comprising an alkali metal chlorite.

22. The method according to claim 21, wherein the alkali metal chlorite is sodium chlorite.

23. The method according to claim 22, wherein the sodium chlorite has a concentration of no more than approximately 5000 parts per million based upon weight of the first formulation.

24. The method according to claim 6, the first formulation having a pH of about 7.5 to about 9.

25. The method according to claim 6, the second formulation having a pH of about 3.0 to about 4.5.

26. The method according to claim 6, interface having a pH from about 3.0 to about 6.0.

27. The method according to claim 6, the interface having a pH from about 3.0 to about 4.5.

28. The method according to claim 6, wherein the first formulation is a liquid and the second formulation is a gel.

* * * * *

the top surface, were stained in a manner to duplicate the tooth staining observed in vivo by humans (alternately exposed to air and a staining broth at 37 degrees C. containing typticase soy broth, tea, coffee, mucin, $FECl_3$, and *Sarcina lutea*, for a period of about four days). Each stained bovine incisor was numbered and measured for degree of staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer (3 mm aperture, 8 exposure averaging, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes, whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below ΔE. Absolute color change is defined as the square root of the sum of the squares of all color components (L, a, and b).

$$\sqrt{(\Delta L)^2+(\Delta a)^2+(\Delta b)^2}=\Delta E$$

TABLE 4

Tooth #	Product/ Example	pH (neat)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5 (2) to 6.0 (3) results in an increased ΔE from 4.29 to 6.27.

The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent wireless 1B and 1C contained a chelating agent. There was an observed improvement in ΔE in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

Opalescence is a commercial product which has been pH adjusted to pH 6.5 before use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

EXAMPLE 5

In Vivo Demonstration of Tooth Bleaching

Six volunteers aged 25 to 43 were separated into two groups of two and customer dental trays were fashioned for each participant in the study.

One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

Patient #	Product/ Example	Treatment Time (minutes)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65
4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

The average ΔE for the Example 1B group was 7.32, whereas the average ΔE for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

I claim:

1. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising:

hydrogen peroxide in an effective tooth whitening amount,

an aqueous matrix comprising

a calcium chelating agent,

a thickening agent, and

an alkaline pH adjusting agent,

wherein the mixture has a pH above 5.5 and wherein the mixture was packaged as a one component system.

2. The mixture of claim 1, wherein the water content is at least 70% by weight, based on the weight of the composition.

3. The mixture of claim 1, wherein the thickening agent is a high molecular weight crosslinked polyacrylic acid.

4. The mixture of claim 1, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the composition.

5. The mixture of claim 1, wherein the aqueous mixture has a water content of at least 75% by weight, based on the weight of the composition.

6. The mixture of claim 1, wherein the matrix also has a stabilizing agent selected from the group consisting of sodium stannate trihydrate, 1-Hydroxyethylidene-1,1-diphosphonic acid, and combinations thereof.

7. The mixture of claim 6, wherein the stabilizing agent may also act as a calcium chelating agent.

8. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising:

hydrogen peroxide,

an aqueous matrix comprising a high molecular weight crosslinked polyacrylic acid in an amount between approximately 2.0% and approximately 5.0% by weight, based on the weight of the mixture,

an alkaline pH adjusting agent, and

sodium stannate trihydrate or 1-Hydroxyethylidene-1,1-diphosphonic acid, in an amount between approximately 0.02% and approximately 0.5% by weight, based on the weight of the mixture,

wherein the mixture has a pH above 5.5 and wherein the mixture is packaged as a single component system.

9. The mixture of claim 8, wherein the concentration of hydrogen peroxide in the composition is less than 15% by weight of the composition.

10. The mixture of claim 8, wherein the matrix also has a concentration of a calcium chelating agent of between approximately 0.02% and approximately 0.4% by weight, based on the weight of the composition.

11. The mixture of claim 8, wherein the stabilizing agent may also act as a calcium chelating agent.

12. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising

hydrogen peroxide in an effective tooth whitening amount,

a thickening agent,

water,

an alkalizing agent, and

a calcium chelating agent,

wherein the tooth bleaching mixture has a pH above 5.5 and wherein the tooth bleaching mixture is single a component system.

13. The mixture of claim 12 wherein the calcium chelating agent is a member selected from the group consisting of EDTA, salts of EDTA, citric acid, salts of citric acid, gluconic acid, salts of gluconic acid, alkali metal pyrophosphates and alkali metal polyphosphates.

14. A tooth bleaching mixture for contacting a tooth surface in an oral cavity comprising

hydrogen peroxide in an effective tooth whitening amount,

a thickening agent,

water,

a stabilizing agent, and

an alkalizing agent

wherein the stabilizing agent is a member selected from the group consisting of sodium acid pyrophosphate, sodium stannate trihydrate, and 1-hydroxyethylidene-1,1-diphosphonic acid.

* * * * *

TABLE 5-continued

Patient	Product/	Treatment	Initial Color			Final Color			
#	Example	Time (minutes)	L	a	b	L	a	b	ΔE
4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

The average ΔE for the Example 1B group was 7.32, whereas the average ΔE for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

What is claimed is:

1. A method for whitening the teeth of a subject comprising:

providing a multi chamber vessel, the vessel including a first chamber having a first formulation comprising a hydrogen peroxide precursor compound and an anhydrous carrier wherein the first formulation is substantially free of an alkaline pH adjusting agent; and

a second chamber having a second formulation comprising an alkaline pH-adjusting agent and wherein the second formulation is substantially free of the hydrogen peroxide precursor compound;

the first formulation or the second formulation including a thickener and

applying pressure to the multi chamber vessel so as to force the first and second formulations through a mixer to form a mixture which then emerges from a single exit, the mixture being a thickened, aqueous hydrogen peroxide containing composition having a pH of greater than 5.5; and

contacting the mixture to the teeth of the subject for less than one hour.

2. A method for whitening the teeth of a subject comprising:

providing a multi chamber vessel, the vessel including a first chamber having a first formulation comprising hydrogen peroxide and an aqueous carrier wherein the first formulation is substantially free of an alkaline pH adjusting agent; and

a second chamber having a second formulation comprising an alkaline pH-adjusting agent and wherein the second formulation is substantially free of hydrogen peroxide;

the first formulation or the second formulation including a thickener and

applying pressure to the multi chamber vessel so as to force the first and second formulations through a mixer to form a mixture which then emerges from a single exit, the mixture being a thickened, aqueous hydrogen peroxide containing composition having a pH of greater than 5.5; and

contacting the mixture to the teeth of the subject for less than one hour.

3. The method of claims 1 or 2 wherein the mixture includes a stabilizing agent.

4. The method of claims 1 or 2 wherein the mixture includes a calcium chelating agent.

5. The method of claims 1 or 2 wherein the mixture has a pH within a range of between about 6 to about 10.

6. The method of claims 1 or 2 wherein the mixture has a pH within a range of between about 7 to about 10.

7. The method of claims 1 or 2 wherein the mixture includes at least 70% water by weight, based on the weight of the mixture.

8. The method of claim 1 wherein the hydrogen peroxide precursor compound is a member selected from the group consisting of an alkali metal percarbonate, carbamide peroxide, calcium peroxide and an alkali metal perborate.

9. The method of claim 1 wherein the anhydrous carrier is a member selected from the group consisting of glycerine, propylene glycol and polyethylene glycol.

10. The method of claims 1 or 2 wherein the alkaline pH adjusting agent is a member selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine.

11. The method of claim 3 wherein the stabilizing agent is a member selected from the group consisting of sodium acid pyrophosphate, sodium stannate trihydrate, and 1-hydroxyethylidene-1,1-diphosphonic acid.

12. The method of claim 4 wherein the calcium chelating agent is a member selected from the group consisting of EDTA, salts of EDTA, citric acid, salts of citric acid, gluconic acid, salts of gluconic acid, alkali metal pyrophosphates and alkali metal polyphosphates.

13. The method of claims 1 or 2 wherein the thickener is a high molecular weight crosslinked polyacrylic acid.

14. The method of claim 2 wherein the mixture has a hydrogen peroxide concentration of less than 15% by weight of the mixture.

15. The method of claim 3 wherein the stabilizing agent may also act as a calcium chelating agent.

16. The method of claims 1 or 2 wherein the mixture has a pH within a range of between approximately 7.5 and approximately 9.0.

17. The method of claims 1 or 2 wherein the mixture has a pH of approximately 8.0.

18. A method for whitening the teeth of a subject comprising:

providing a kit including a first tube and a second tube, the tubes adapted to keep apart two formulations, the first tube and the second tube respectively include:

a first formulation comprising hydrogen peroxide and an aqueous carrier wherein the first formulation is substantially free of an alkaline pH adjusting agent; and

a second formulation comprising an alkaline pH-adjusting agent and wherein the second formulation is substantially free of the hydrogen peroxide;

the first formulation or the second formulation including a thickener and mixing the first formulation and the second formulation to form a thickened, aqueous, hydrogen peroxide containing mixture, wherein the mixture has a pH of greater than 5.5; and

contacting the mixture to the teeth of the subject for less than one hour.

19. The method of claim 18 wherein the mixture includes a stabilizing agent.

20. The method of claim 18 wherein the mixture includes a calcium chelating agent.

21. The method of claim 18 wherein the mixture has a pH within a range of between about 6 to about 10.

22. The method of claim 18 wherein the mixture has a pH within a range of between about 7 to about 10.

23. The method of claim 18 wherein the mixture includes at least 70% water by weight, based on the weight of the mixture.

24. The method of claim 18 wherein the alkaline pH adjusting agent is a member selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine.

25. The method of claim 19 wherein the stabilizing agent is a member selected from the group consisting of sodium acid pyrophosphate, sodium stannate trihydrate, and 1-hydroxyethylidene-1,1-diphosphonic acid.

26. The method of claim 20 wherein the calcium chelating agent is a member selected from the group consisting of EDTA, salts of EDTA, citric acid, salts of citric acid, gluconic acid, salts of gluconic acid, alkali metal pyrophosphates and alkali metal polyphosphates.

27. The method of claim 18 wherein the thickener is a high molecular weight crosslinked polyacrylic acid.

28. The method of claim 18 wherein the mixture has a hydrogen peroxide concentration of less than 15% by weight of the mixture.

29. The method of claim 19 wherein the stabilizing agent may also act as a calcium chelating agent.

30. The method of claim 18 wherein the mixture has a pH within a range of between approximately 7.5 and approximately 9.0.

31. The method of claim 18 wherein the mixture has a pH of approximately 8.0.

* * * * *

staining (color by the CIELAB protocol) with a Minolta 5031 Spectrophotometer (3mm aperture, 8 exposure averaging, outliers discarded). Incisors were covered with different tooth-bleaching compositions in the tables above, in addition to a commercially available carbamide peroxide composition (Opalescence 10% Carbamide Peroxide Gel, Ultradent, South Jordan, Utah). All gels were kept in contact with the incisor surface for exactly 15 minutes, whereupon the tooth was rinsed clean of any gel residue with distilled water and swabbed with saliva. The degree of stain removal was thereafter immediately determined by measuring the incisor surface, as above, for color, and the change in tooth color recorded below as ΔE. Absolute color change is defined as the square root of the sum of the squares of all color components (L, a, and b).

$$\sqrt{[(\Delta L)^2+(\Delta a)^2]}=\Delta E$$

TABLE 4

Tooth #	Product/ Example	pH (neat)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	Opalescence	6.5	41.79	3.17	11.78	44.29	2.96	11.70	2.51
2	Example 3	4.5	39.84	4.99	12.00	43.96	4.47	10.94	4.29
3	1E	6.0	40.44	4.41	9.53	46.32	3.48	7.54	6.27
4	1A	7.0	36.02	3.84	10.10	42.57	2.59	8.28	6.91
5	1B	7.0	38.81	3.98	11.38	45.92	2.38	8.81	7.73
6	1C	7.0	36.90	4.05	12.61	44.11	2.45	10.53	7.67
7	1D	8.0	41.55	3.67	10.51	49.77	1.26	7.82	8.98
8	1F	6.5	38.55	5.01	10.87	44.78	3.67	9.50	6.52
9	1G	8.5	40.26	4.59	9.93	48.28	3.13	7.97	8.38
10	Example 2	9.0	36.49	4.00	12.64	44.93	2.20	10.63	8.78

This table shows the effect of pH on tooth bleaching. As shown for tooth #2 treated with the formulation of Example 3 and tooth #3 treated with the formulation of 1E in Example 1, the increase in pH from 4.5 (2) to 6.0 (3) results in an increased ΔE from 4.29 to 6.27.

The table further shows the positive effect of the calcium chelating agent on tooth bleaching. For example, for 1A, 1B, and 1C (all at pH 7.0), 1A lacked a calcium chelating agent whereas 1B and 1C contained a chelating agent. There was an observed improvement in ΔE in the presence of the chelating agent. The best tooth-bleaching results were obtained at the highest pH, namely, in this experiment, pH 8.0 and pH 9.0.

Opalescence is a commercial product which has been pH adjusted to pH 6.5 before use but shows a poor performance with regard to color change over the time of the experiment. It is proposed that the pH of the formulation is lowered as hydrogen peroxide and urea is released following dissociation of carbamide peroxide.

Example 5: In vivo demonstration of tooth bleaching

Six volunteers aged 25 to 43 were separated into two groups of two and custom dental trays were fashioned for each participant in the study.

One group was given an unmarked 2 oz. tube containing the composition of Example 1B and instructed to place a small amount of tooth-bleaching material into the tray, position the tray over the teeth, and leave the tray in place for 20 minutes. Patients were instructed to repeated this procedure twice a day for one week, for a total of 14 treatments and 280 minutes total tooth whitener exposure time.

The second group was given an unmarked 2 oz. tube of Opalescence 10% Carbamide Peroxide tooth-bleaching gel and instructed as above, with the exception of the duration of the bleaching procedure to be 60 minutes. Patients were instructed to repeat the procedure twice a day for one week, for a total of 14 treatments and 840 minutes total tooth-bleaching exposure time.

The results of direct tooth surface (upper left central incisor) color measurements, both before and after treatment (as in Example 5 above), are recorded in the Table 5 below.

TABLE 5

Patient #	Product/ Example	Treatment Time (minutes)	Initial Color L	a	b	Final Color L	a	b	ΔE
1	1B	280	53.76	4.65	11.65	60.34	0.97	8.80	8.06
2	1B	280	49.42	2.97	9.48	56.99	0.46	7.38	8.25
3	1B	280	51.26	2.33	8.25	55.63	0.87	4.99	5.65
4	Opalescence	840	52.78	1.75	6.14	57.26	1.42	2.10	6.04
5	Opalescence	840	56.35	1.79	5.21	59.13	0.65	2.44	4.09
6	Opalescence	840	55.71	2.72	7.10	58.60	1.09	4.75	4.07

The average ΔE for the Example IB group was 7.32, whereas the average ΔE for the Opalescence group was 4.73. The present inventive compositions are thus shown to offer a substantially improved degree of tooth bleaching in a shorter exposure time than a prior art composition.

I claim:

1. A single exit multi compartment vessel with a mixer, whose compartments are adapted to keep apart two formulations and whose compartments respectively include:

a first formulation comprising a hydrogen peroxide precursor compound and an anhydrous carrier wherein the

first formulation is substantially free of an alkaline pH adjusting agent; and

a second formulation comprising an alkaline pH-adjusting agent and wherein the second formulation is substantially free of the hydrogen peroxide precursor compound;

the first formulation or the second formulation including a thickener and whereby applying pressure to the vessel forces material from the compartments through the mixer to form a thickened, aqueous hydrogen peroxide containing mixture emerging from the single exit in the vessel, wherein the mixture has a pH of greater than 5.5.

2. A single exit multi compartment vessel with a mixer, whose compartments are adapted to keep apart two formulations and whose compartments respectively include:

a first formulation comprising hydrogen peroxide and an aqueous carrier wherein the first formulation is substantially free of an alkaline pH adjusting agent; and

a second formulation comprising an alkaline pH-adjusting agent and wherein the second formulation is substantially free of the hydrogen peroxide;

the first formulation or the second formulation including a thickener and whereby applying pressure to the vessel forces material from the compartments through the mixer to form a thickened, aqueous hydrogen peroxide containing mixture emerging from the single exit in the vessel, wherein the mixture has a pH of greater than 5.5.

3. The vessel of claims 1 or 2 wherein the mixture includes a stabilizing agent.

4. The vessel of claims 1 or 2 wherein the mixture includes a calcium chelating agent.

5. The vessel of claims 1 or 2 wherein the mixture has a pH within a range of between about 6 to about 10.

6. The vessel of claims 1 or 2 wherein the mixture has a pH within a range of between about 7 to about 10.

7. The vessel of claims 1 or 2 wherein the mixture includes at least 70% water by weight, based on the weight of the mixture.

8. The vessel of claim 1 wherein the hydrogen peroxide precursor compound is a member selected from the group consisting of an alkali metal percarbonate, carbamide peroxide, calcium peroxide and an alkali metal perborate.

9. The vessel of claim 1 wherein the anhydrous carrier is a member selected from the group consisting of glycerine, propylene glycol and polyethylene glycol.

10. The vessel of claims 1 or 2 wherein the alkaline pH adjusting agent is a member selected from the group consisting of alkali metal hydroxides, ammonium hydroxide, alkali metal carbonates, TRIS, and triethanolamine.

11. The vessel of claim 3 wherein the stabilizing agent is a member selected from the group consisting of sodium acid pyrophosphate, sodium stannate trihydrate, and 1-hydroxyethylidene-1,1-diphosphonic acid.

12. The vessel of claim 4 wherein the calcium chelating agent is a member selected from the group consisting of EDTA, salts of EDTA, citric acid, salts of citric acid, gluconic acid, salts of gluconic acid, alkali metal pyrophosphates and alkali metal polyphosphates.

13. The vessel of claims 1 or 2 wherein the thickener is a high molecular weight crosslinked polyacrylic acid.

14. The vessel of claim 2 wherein the mixture has a hydrogen peroxide concentration of less than 15% by weight of the mixture.

15. The vessel of claim 3 wherein the stabilizing agent may also act as a calcium chelating agent.

16. The vessel of claims 1 or 2 wherein the mixture has a pH within a range of between approximately 7.5 and approximately 9.0.

17. The vessel of claims 1 or 2 wherein the mixture has a pH of approximately 8.0.

* * * * *

TABLE 5

COMPONENT	AMOUNT
Light Mineral Oil USP	87 grams
Sodium Percarbonate (Solvay-FB100)	10 grams
Malic Acid (Powder FCC)	3 grams
TOTAL	100 grams

The above components were slurried until a fine dispersion of solids was obtained. Agitation continued during the spray process to prevent the settling out of the solids. The sprayed rawhide chews were dried at room temperature for 24 hours, during which time the initial surface gloss observed on the freshly sprayed chews disappeared.

In order to determine the ability of the spray-coated rawhide chew to generate pH-adjusted hydrogen peroxide upon contact with water, single chews cut into four pieces and weighed. An equivalent amount of distilled water was weighed out and the coated chews vortexed in the water for 15 seconds. The Achew fluid@ contained a hydrogen peroxide concentration of 6.53 millimolar at a pH of 5.84 at 25° C.

Example V

Delivery of the Oral Composition in a Gel

An anhydrous carbamide peroxide gel composition was prepared in order to demonstrate another option for delivery of the composition to the oral cavity.

TABLE 6

COMPONENT	AMOUNT
Glycerine 99.7% USP	93.45 grams
Carbopol 980 NF (BF Goodrich)	2.00 grams
Carbamide Peroxide (Degussa) USP	0.05 grams
Distilled Water	3.00 grams
Tris(hydroxymethyl)aminomethane USP	1.50 grams
TOTAL	100 grams

The Carbopol 980 NF was dispersed under high shear in the Glycerine 99.7% USP and subsequently deaerated. The Carbamide Peroxide was then dissolved in this mixture under low shear mixing. The Tris(hydroxymethyl) aminomethane was dissolved in the Distilled Water, and this phase dispersed into the main phase under 28@ Hg vacuum in order to avoid entrapment of air. The resulting gel was highly viscous and transparent.

In the above composition, the tris(hydroxymethyl) aminomethane USP serves as both a neutralizer for thickening the acidic carboxypolymethylene (Carbopol 980 NF) and as an alkalizer to provide a suitable peroxidase-active pH during the use of this product. The pH of a 1:5 dilution (1 part Example V to 5 parts Distilled Water) is 5.4, and the dilution showed a hydrogen peroxide concentration of 969 micromoles per liter.

I claim:

1. An oral care composition for activating a peroxidase system in an animal oral cavity, comprising:

a non-aqueous or otherwise substantially water-free dentifrice;

a non-enzymatic, water-soluble, finely divided hydrogen peroxide precursor material incorporated within the dentifrice, the material capable of rapidly releasing an effective amount of hydrogen peroxide for activating the peroxidase system in the oral cavity upon contact with an aqueous solution, the material coated or encapsulated by being dispersed in a water insoluble, non-hygroscopic, viscous fluid or in a film-forming, melt-processable waxy solid, the fluid or solid selected from the group consisting of:

(a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or (b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcohols the fluid or solid being a non-solvent of the material; and

a pH-adjusting agent capable of producing a selected pH of between about 4.0 and about 6.5 in the aqueous solution.

2. A composition according to claim 1, wherein the material is finely divided sodium percarbonate.

3. A composition according to claim 1, wherein the material is finely divided carbamide peroxide.

4. A composition according to claim 1, wherein the material is finely divided calcium peroxide.

5. A composition according to claim 1, further comprising:

an abrasive.

6. A composition according to claim 1, further comprising:

a flavorant.

7. A composition according to claim 1, further comprising:

a thickener.

8. A composition according to claim 1, further comprising:

an alkali metal thiocyanate.

9. A composition according to claim 8, further comprising:

a peroxidase enzyme.

10. A process for manufacturing an oral care composition, comprising:

obtaining non-enzymatic, water-soluble,finely divided hydrogen peroxide precursor material,

providing a non-aqueous or otherwise substantially water-free dentifrice,

dispersing the finely divided hydrogen peroxide precursor material in a water insoluble, non-hygroscopic, viscous fluid or in a film-forming, melt-processable waxy solid, the fluid or solid selected from the group consisting of:

(a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or (b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcohols, the fluid or solid being a non-solvent of the finely divided hydrogen peroxide precursor material, so as to coat or encapsulate the finely divided hydrogen peroxide precursor material,

associating the finely divided hydrogen peroxide precursor material with a pH-adjusting agent capable of producing a selected pH of between about 4.0 and about 6.5 in an aqueous solution, and

incorporating the associated material within the dentifrice.

11. A method of activating a peroxidase system in an oral cavity of an animal, comprising:

selecting non-enzymatic, water-soluble, finely divided hydrogen peroxide precursor material capable of rapidly releasing an effective amount of hydrogen peroxide for activating the peroxidase system in the oral cavity upon contact with an aqueous solution, the material coated or encapsulated by being dispersed in a water insoluble, non-hygroscopic, viscous fluid or in a film-forming, melt-processable waxy solid, the fluid or solid selected from the group consisting of:

(a) liquid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons and fluorosilicones, or (b) solid mineral oils, vegetable oils, fatty esters, silicone fluids, fluorinated hydrocarbons, fluorosilicones, stearic acid, glycerin monosterate, paraffin wax, microcrystalline wax, and fatty alcohols, the fluid or solid being a non-solvent of the material,

mixing the material with a pH-adjusting agent capable of producing a selected pH of between about 4.0 and about 6.5 in the aqueous solution, and

administering to the oral cavity, the material and pH-adjusting agent incorporated within a non-aqueous or otherwise substantially water-free dentifrice.

* * * * *

Attorney Docket No. 03131437

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of:

R. Eric MONTGOMERY

Serial No.: TBA

Filed: May 9, 2003

For: LIGHT-ACTIVATED TOOTH WHITENING COMPOSITION AND METHOD OF USING SAME

Examiner: TBA

Group Art Unit: TBA

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
"Express Mail" mailing label number EV 113373318 US
Date of Deposit: MAY 9, 2003
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the date indicated above and is addressed to U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

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TRANSMITTAL LETTER

Commissioner for Patents
Box Patent Application
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed herewith are the following for the above-captioned application:

1. Utility Patent Application Transmittal;
2. Fee Transmittal Form;
3. Continuation-In-Part Application with Specification with Claims and Abstract;
4. Drawings;
5. Executed Combined Declaration and Power of Attorney;
6. Return-receipt postcard.

The Commissioner is hereby authorized to charge any additional filing fees required under Rule 1.17 concerning this transaction, or to credit any overpayment to Deposit Account 13-0019.

Respectfully submitted,

MAYER, BROWN, ROWE & MAW

By: Christine M. REBMAN
Reg. No. 50546

Dated: MAY 9, 2003

MAYER, BROWN, ROWE & MAW
P.O. Box 2828
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PTO/SB/05 (03-01)
Approved for use through 10/31/2002. OMB 0651-0032
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	03131437
First Inventor	R. Eric MONTGOMERY
Title	LIGHT-ACTIVATED TOOTH WHITENING COMPOSITION...
Express Mail Label No.	EV 113373318 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. [✔] Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [ ] Applicant claims small entity status. See 37 CFR 1.27.
3. [✔] Specification [*Total Pages* 57] *(preferred arrangement set forth below)*
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. [✔] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 10]
5. Oath or Declaration [*Total Pages* 3]
   a. [✔] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63 (d)) *(for continuation/divisional with Box 18 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. [ ] Application Data Sheet. See 37 CFR 1.76
7. [ ] CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] paper
   c. [ ] Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. [ ] Assignment Papers (cover sheet & document(s))
10. [ ] 37 CFR 3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
11. [ ] English Translation Document *(if applicable)*
12. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
13. [ ] Preliminary Amendment
14. [✔] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [ ] Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. [ ] Other: .....

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:*

[ ] Continuation [ ] Divisional [✔] Continuation-in-part (CIP) of prior application No.: 09 / 651,170

Prior application information: Examiner: Shep Rose Group Art Unit: 1614

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

[✔] *Customer Number or Bar Code Label* [redacted] CUSTOMER NUMBER 26565

Name	Christine M. REBMAN				
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Name (Print/Type)	Christine M. REBMAN	*Registration No. (Attorney/Agent)*	50546
Signature	Christine M. Rebman	*Date*	05/09/2003

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PROPRIETARY

PTO/SB/17 (05-03)
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FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) $1,254

Complete If Known	
Application Number	TBA
Filing Date	May 9, 2003
First Named Inventor	R. Eric MONTGOMERY
Examiner Name	TBA
Art Unit	TBA
Attorney Docket No.	03131437

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: 13-0019

Deposit Account Name: Mayer, Brown, Rowe & Maw

The Director is authorized to: *(check all that apply)*

☑ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	$750.00
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 750.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below	Fee Paid
Total Claims	48	-20** = 28	x	18	= $504
Independent Claims	3	- 3** = 0	x	0	= 0
Multiple Dependent				0	= 0

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) $504.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($)

SUBMITTED BY				(Complete *if applicable*)	
Name (Print/Type)	Christine M. REBMAN	*Registration No. (Attorney/Agent)*	50546	*Telephone*	312-701-7174
Signature	Christine M Reb			*Date*	May 9, 2003

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PROPRIETARY

LIGHT-ACTIVATED TOOTH WHITENING COMPOSITION AND METHOD OF USING SAME

RELATED APPLICATIONS DATA

This application is a continuation-in-part of application Ser. No. 09/651,170, filed August 30, 2000, which is a continuation of application Ser. No. 09/234,038, filed January 19, 1999 now U.S. Pat. No. 6,162,055, which claims priority to U.S. Provisional No. 60/074,708, filed February 13, 1998 and U.S. Provisional application No. 60/075,222, filed February 19, 1998. This application also claims priority to application Ser. No. 09/483,526, filed January 14, 2000. All of the foregoing applications are hereby incorporated by reference to the extent permitted by law.

FIELD OF THE INVENTION

The present invention relates to compositions and methods for tooth whitening.

BACKGROUND OF THE INVENTION

This invention relates to improvements in tooth whitening compositions and methods of using same. In particular, the invention provides novel tooth whitening compositions and methods that use light energy to achieve a faster and improved level of tooth whitening.

White teeth have long been considered cosmetically desirable. Unfortunately, due to the presence of chromogenic (color-causing) substances in food, beverages, tobacco, and salivary fluid, in addition to internal sources such as blood, amalgam restoratives, and antibiotics such as tetracycline, teeth become almost invariably discolored in the absence of intervention. The tooth structures that are generally responsible for presenting a stained appearance are enamel, dentin, and the acquired pellicle. Tooth enamel is predominantly formed from inorganic material, mostly in the form of hydroxyapatite crystals, and further contains approximately 5% organic material primarily in the form of collagen. In contrast, dentin is composed of about 20% protein including

collagen, the balance consisting of inorganic material, predominantly hydroxyapatite crystals, similar to that found in enamel. The acquired pellicle is a proteinaceous layer on the surface of tooth enamel which reforms rapidly after an intensive tooth cleaning.

Tooth stains may be either extrinsic or intrinsic, depending upon their location within the tooth surface. For example, extrinsic staining of the acquired pellicle arises as a result of compounds such as tannins and other polyphenolic compounds which become trapped in and tightly bound to the proteinaceous layer on the surface of the teeth. This type of staining can usually be removed by mechanical methods of tooth cleaning that remove all or part of the acquired pellicle together with the associated stain. In contrast, intrinsic staining occurs when chromogens or prechromogens penetrate the enamel and dentin and become tightly bound to the tooth structure. Intrinsic staining may also arise from systemic sources of chromogens or prechromogens, for instance, when excess fluoride intake during enamel development leads to the mottled yellow or brown spots typical of fluorosis staining. Intrinsic staining is not amenable to mechanical methods of tooth cleaning and generally requires the use of chemicals, such as hydrogen peroxide, that can penetrate into the tooth structure, in order to affect a change in the light absorptivity of the chromogen. Intrinsic tooth staining is generally more intractable and difficult to remove than extrinsic tooth staining.

Consequently, tooth-bleaching compositions generally fall into two categories: (1) gels, pastes, or liquids, including toothpastes that are mechanically agitated at the stained tooth surface in order to affect tooth stain removal through abrasive erosion of stained acquired pellicle; and (2) gels, pastes, or liquids that accomplish the tooth-bleaching effect by a chemical process while in contact with the stained tooth surface for a specified period, after which the formulation is

removed. In some cases, an auxiliary chemical process or additive, which may be oxidative or enzymatic, supplements the mechanical process.

Among the chemical strategies available for removing or destroying tooth stains, the most effective compositions contain an oxidizing compound, such as hydrogen peroxide, in order to attack the chromogen molecules in such a way as to render them colorless, water-soluble, or both. In one of the most popular approaches to whitening a patient's teeth, a dental professional will construct a custom-made tooth-bleaching tray for the patient from an impression made of the patient's dentition and prescribe the use of an oxidizing gel to be dispensed into the tooth-bleaching tray and worn intermittently over a period of time ranging from about 2 weeks to about 6 months, depending upon the severity of tooth staining. These oxidizing compositions, usually packaged in small plastic syringes, are dispensed directly by the patient, into the custom-made tooth-bleaching tray, held in place in the mouth for contact times of greater than about 60 minutes, and sometimes as long as 8 to 12 hours. The slow rate of bleaching is in large part the consequence of the very nature of formulations that are developed to maintain stability of the oxidizing composition. The most commonly used oxidative compositions contain the hydrogen peroxide precursor carbamide peroxide which is mixed with an anhydrous or low-water content, hygroscopic viscous carrier containing glycerin and/or propylene glycol and/or polyethylene glycol. When contacted by water, carbamide peroxide dissociates into urea and hydrogen peroxide. Associated with the slow rate of bleaching in the hygroscopic carrier, the currently available tooth-bleaching compositions cause tooth sensitization in over 50% of patients. Tooth sensitivity is believed to result from the movement of fluid through the dentinal tubules, which is sensed by nerve endings in the tooth. The carriers for the carbamide peroxide enhance this movement. In fact, it has been determined that glycerin, propylene glycol and polyethylene

glycol can each give rise to varying amounts of tooth sensitivity following exposure of the teeth to heat, cold, overly sweet substances, and other causative agents.

Prolonged exposure of teeth to bleaching compositions, as practiced at present, has a number of adverse effects in addition to that of tooth sensitivity. These include: solubilization of calcium from the enamel layer at a pH less than 5.5 with associated demineralization; penetration of the intact enamel and dentin by the bleaching agents, so as to reach the pulp chamber of a vital tooth thereby risking damage to pulpal tissue; and dilution of the bleaching compositions with saliva resulting in leaching from the dental tray and subsequent ingestion.

Alternatively, there are oxidizing compositions (generally those with relatively high concentrations of oxidizers) which are applied directly to the tooth surface of a patient in a dental office setting under the supervision of a dentist or dental hygienist. Theoretically, such tooth whitening strategies have the advantage of yielding faster results and better overall patient satisfaction; however, due to the high concentration of oxidizing compounds contained in these so called "in-office" compositions, they can be hazardous to the patient and practitioner alike if not handled with care. The patient's soft tissues (the gingiva, lips, and other mucosal surfaces) must first be isolated from potential exposure to the active oxidizing compound by the use of a perforated rubber sheet (known as a rubber dam), through which only the teeth protrude. Alternatively, the soft tissue may be isolated from the oxidizers to be used in the whitening process by covering said soft tissue with a polymerizable composition that is shaped to conform to the gingival contours and subsequently cured by exposure to a high intensity light source. Once the soft tissue has been isolated and protected, the practitioner may apply the oxidizing compound directly onto the stained tooth surfaces for a specified period of time or until a sufficient change in tooth color has occurred. Typical results obtained through the use of a in-

office tooth whitener, with or without activation by heat, range from about 2 to 3 shades (as measured with the VITA® Shade Guide, VITA® Zahnfarbik, Bad Sackingen, Germany).

The range of tooth shades in the VITA® Shade Guide varies from very light (B1) to very dark (C4). A total of 16 tooth shades constitute the entire range of colors between these two endpoints on a scale of brightness. Patient satisfaction with a tooth whitening procedure increases with the number of tooth shade changes achieved. Typically, the minimum generally accepted change is about 4 to 5 VITA® shades.

Attempts have been made to activate peroxides with heat and/or light for the purpose of whitening teeth. U.S. Pat. No. 4,661,070 discloses a method of whitening stained teeth which includes the application of a concentrated solution of hydrogen peroxide within the pulp chamber or upon the surface of a discolored tooth, followed by exposing the discolored tooth to optical energy consisting of both ultraviolet and infrared light. The preferred wavelengths of light disclosed by this patent are from 320 to 420 nanometers and from 700 to 1200 nanometers, with light in the visible spectrum (wavelengths from 500 and 700 nanometers) being suppressed. The disclosed method suffers from two serious drawbacks: (1) ultraviolet light can be hazardous to the patient and practitioner alike and (2) infrared light may cause irreversible pulpitis if not handled with care.

These drawbacks are partially addressed in U.S. Pat. No. 4,952,143 which discloses a dental bleaching instrument which filters out ultraviolet light and has a temperature regulation mechanism. This patent also discloses the use of visible light with wavelengths ranging from 450 to 500 and 650 to 750 nanometers to produce a dark reddish/purple beam which facilitates the aiming and focusing of the instrument.

U.S. Pat. No. 5,032,178 discloses compositions and methods to improved tooth whitening efficacy which uses exposure to "optical energy", preferably in the visible spectrum wavelength range of 400 to 700 nanometers. The compositions disclosed in this patent require the use of (1) an inert silica gelling agent, (2) a catalytic accelerator (either manganese sulfate monohydrate or ferrous sulfate), (3) an agent for providing thixoplasticity and thickening properties to the composition, such as cellulose ethers and methyl vinyl ethers, and (4) a means for indicating completion of the bleaching treatment of the teeth, comprising a redox color indicator for transforming from one color to another in response to the dissociation of hydrogen peroxide over a given time period. Compositions described therein are mixed homogeneously prior to use and all of the required components, including the catalyst, are dispersed evenly throughout the mixture. The compositions described are not highly transparent to light energy in the range of 400 to 700 nm, due to the presence of the high levels of inorganic silica particles. Commercial mixtures based on this patent (available under the trade name Shofu Hi-Lite® from Shofu Dental Corporation, Menlo Park, Calif.) confirm that these preparations are not transparent to visible light, but rather are quite opaque. Typical results obtained using such compositions and methods are about 2 to 3 VITA® shades improvement in tooth color, similar to that achieved with compositions that do not employ light energy in the process of bleaching teeth.

U.S. Pat. No. 5,240,415 discloses a dental bleaching system comprising a multi-component kit, one of the required components of said kit being fumed silica. As described above, silica renders an aqueous composition relatively opaque to visible light energy. Again, a tooth shade improvement of about 2 to 3 VITA® shades can be expected through the use of this type of composition.

A commercial product called Opalescence Xtra available for bleaching teeth in the controlled environment of a dental office has recently been introduced by Ultradent Products, Inc, South Jordan, Utah. This product is believed to be based on the disclosure of U.S. Pat. No. 5,785,527. The commercial product is supplied in a plastic syringe and is described in the accompanying literature as a light-activated tooth whitening gel, which contains approximately 35% hydrogen peroxide. A pH determination showed the product to have a neat pH at 25° C. of about 4.0. The product is thickened to a loose, gel-like consistency with a polymer. Additionally, the product as sold, and as disclosed in U.S. Pat. No. 5,785,527, contains a bright orange pigment or dye (carotene), which presumably serves as the "photosensitizer". The manufacturer also claims that the photosensitizer is able to absorb light energy and convert it into heat energy, thereby increasing the activity of the peroxide as a tooth bleaching compound. The presence of a photoabsorber in the aforementioned composition renders it relatively opaque to wavelengths from about 400 to 700 nm. Exposure of this composition to light energy between 400 and 700 nm results in a gradual fading of the orange color, presumably due to a photobleaching effect in the presence of the hydrogen peroxide. Comparative clinical results show an improvement in tooth color of from about 3 to 4 VITA®.shades, which is highly dependent upon the contact time of the composition on the tooth surface, rather than any particular light or heat activation regimen. In addition, the low pH of the commercial product may cause a reduction in the microhardness of tooth enamel, due to the dissolution of hydroxyapatite crystals (which can occur at a pH of around 5.5 or less).

Devices for use in light/heat-activated tooth whitening procedures include the commercially available Union Broach Illuminator System, from Union Broach, a Health\Chem Company, New York, N.Y. This device, as described by the manufacturer, provides direct, full

spectrum illumination to all of the teeth found in the front of the average adult's mouth. However, this device does not uniformly illuminate all sixteen central teeth in the front upper and lower arches because of the curvature of the dentition. This potentially gives rise to uneven results. In addition, the Union Broach device generates a great deal of heat which is both uncomfortable for the patient and potentially damaging to the teeth.

There is thus a need for improved compositions, methods and devices for whitening teeth that overcome the limitations of the prior art described above. In particular, there is a need for tooth whitening compositions and methods capable of whitening teeth quickly and safely, without harm to tooth enamel, dentin, or pulp. The compositions and methods of the present invention described herein satisfy these and other needs.

It is an object of this invention to provide fast and safe tooth whitening compositions and methods that can be activated or accelerated by the use of light energy.

It is a further object of this invention to provide a tooth whitening composition that shortens the treatment time required to obtain a given level of tooth whitening that is satisfactory to both the patient and the dentist.

It is another object of the present invention to provide tooth whitening compositions that are relatively transparent to light energy in the wavelength range at which tooth chromogens absorb in order to allow exposure of the tooth enamel surface to said light energy while in contact with said tooth whitening compositions.

It is yet another object of this invention to provide compositions and methods for whitening teeth whereby the extent of tooth whitening, in addition to the types of tooth stains removed, can be controlled by the duration, intensity and wavelength of actinic radiation exposure at the tooth surface.

SUMMARY OF THE INVENTION

The present invention encompasses methods for whitening teeth, wherein a stained tooth surface is contacted with (i) an accelerator composition having a pH range of approximately 7.0 to approximately 10.0 and (ii) an oxidizing composition and, after contacting with the composition and agent, the tooth is exposed to a biologically safe and effective level of photoactinic light in order to enhance the ability of the oxidizing compound in the whitening composition to effect rapid tooth whitening. The accelerator composition may be included in the same composition (for example, mixed with the oxidizing compound just prior to application onto the stained tooth surface) or it may be a separate and distinct composition from the oxidizing compound (for example, applied onto the stained tooth surface in a sequential manner with one or more other compositions). In one method of the present invention, a stained tooth surface is contacted with the accelerator composition prior to contacting the tooth surface with the oxidizing compound. In another embodiment, a stained tooth surface is contacted with the oxidizing composition prior to contacting the tooth surface with the accelerator composition. In yet another embodiment, one of the sequential application methods described above is repeated two or more times over the course of a full tooth whitening procedure.

The present invention encompasses methods for whitening teeth comprising the use of an accelerator composition, wherein the accelerator composition comprises at least one means for accelerating the decomposition of an oxidizing compound in contact with a stained tooth. The accelerator composition may comprise one or more means for accelerating the decomposition of an oxidizing compound in contact with a stained tooth, including an alkaline pH adjusting agent and a photosensitive agent. In another embodiment of the present invention, the accelerator composition comprises both a photosensitive agent and an alkaline pH adjusting agent.

Optionally, any one of the above accelerator compositions may further comprise a performance enhancing adjuvant such as a buffer, penetration enhancer, surfactant, tooth desensitizing agent, a film forming agent, or a thickener.

Also disclosed and contemplated within the scope of this invention are the compositions and compounds described above and devices for whitening teeth, wherein a minimum of eight central teeth in both the upper and lower arches in an adult are simultaneously and uniformly illuminated with a biologically safe and effective level of actinic light to effect rapid tooth whitening.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagram of a device for illuminating the eight central teeth in both the upper and lower arches of an adult for use in a light-activated tooth whitening procedure.

FIG. 2 is a diagram illustrating the position of two devices for illuminating the eight central teeth in both the upper and lower arches of an adult for use in a light-activated tooth whitening procedure.

FIG. 3 is a graph of Comparative Spectra.

FIG. 4A-E are Spectral Curves of Light Attenuation.

FIG. 5 is a graph illustrating the change in pH after addition of acid (HCl) or base (NaOH) to glycine.

FIG. 6 is a histogram of pre-treatment and post-treatment tooth shades utilizing the tooth whitening composition of the present invention.

FIG. 7 is a histogram depicting whitening success factors for starting shades utilizing the tooth whitening composition of the present invention.

DETAILED DESCRIPTION

This section details the preferred embodiments of the subject invention. These embodiments are set forth to illustrate the invention, but are not to be construed as limiting. Since the present disclosure is directed to those skilled in the art field and is not a primer on the manufacture of tooth whitening compositions or their use or on devices for using such compositions, basic concepts and standard features known to those skilled in the art are not set forth in detail. Details for concepts such as choosing appropriate construction materials or ingredients, operating conditions or manufacturing techniques, etc. are known or readily determinable to those skilled in the art. Attention is directed to the appropriate texts and references known to those skilled in the art for details regarding these and other concepts which may be required in the practice of the invention; see, for example, Kirk-Othmer Encyclopedia of Chemical Technology, 4th Edition, Volumes 4 (1992), 13 (1995), 18 (1996), John Wiley & Sons, NY; Goldstein and Garber, Complete Dental Bleaching, Quintessence Publishing Co. 1995; and the aforementioned Journal of the American Dental Association, Vol. 128, Special Supplement, April 1997, the disclosures of which are hereby incorporated by reference into the present disclosure to aid in the practice of the invention.

The development of the inventive compositions and methods described herein resulted from the unexpected discovery that extremely rapid tooth whitening occurs by allowing actinic radiation to penetrate through the oxidizing compound, which is placed directly onto the tooth surface to be whitened. This discovery is antithetical to all prior art compositions that include a light (or heat) absorbing additive dispersed directly in and homogeneously throughout the oxidizing compound. The inventive compositions, on the other hand, allow actinic radiation to reach the stained tooth surface at higher power densities than prior art compositions that are

specifically designed to absorb light. Actinic radiation is thus more effectively utilized compared to prior art compositions and methods in which compositions are both opaque to most wavelengths of light and are activated directly by the actinic radiation. As the greatest oxidizing activity is required in the few millimeters of enamel and dentin at the tooth surface, the present inventive compositions and methods are more effective at removing tooth stains, in many cases with lower levels of active oxidizing compounds, thereby resulting in safer compositions for use in the oral cavity.

For the purpose of this disclosure, the term actinic radiation shall mean light energy capable of being absorbed by either an exogenous photosensitizing agent or oxidizing compound or an indigenous tooth chromogen. Also for the purpose of this disclosure, photosensitizing actinic radiation will mean light absorbed by a specific photosensitive agent or oxidizing compound, whereas chromosensitizing actinic radiation will mean light absorbed by one or more tooth chromogens. The terms "photoactinic light", "actinic radiation" and "actinic light" will be referred to interchangeably.

Also for the purposes of this disclosure, the term "transparent" shall mean having greater than 70% transmission of light at a specified wavelength or within a wavelength range. In addition, all composition ingredient percentages are by weight unless otherwise stated.

The tooth whitening compositions of the present invention include an oxidizing compound and an accelerator. The oxidizing compound may be administered in the same composition or a separate composition from the accelerator. In one embodiment, the tooth whitening composition comprises an oxidizing composition and an accelerator composition that are sequentially applied to a patient's teeth. The accelerator composition may comprise one or both of an alkaline pH adjusting agent and a photosensitive agent. Optionally, a performance

enhancing adjuvant, such as a buffer, a penetration enhancer, a tooth-desensitizing agent, a fluoride compound, a thickener, or a surfactant, may be included, alone or in combination.

Useful oxidizing compounds include liquids and gels, preferably containing a peroxide or peroxyacid known in the art. Such oxidizing compounds include, but are not limited to, hydrogen peroxide, carbamide peroxide, calcium peroxide, magnesium peroxide, zinc peroxide, sodium percarbonate, potassium percarbonate, , potassium persulfate, sodium persulfate, ammonium persulfate, disodium monoperphosphate, dipotassium monoperphosphate, peroxyacids, and magnesium monoperoxyphthalate. Other oxidizing compounds include materials that release hydrogen peroxide upon contact with water, such as an oxidoreductase enzyme and its corresponding substrate, for instance glucose oxidase and glucose. Ozone may also be used alone or in conjunction with one or more of the oxidizing compounds listed herein. Often, it may be desirable to utilize a peroxyacid compound, such as peroxyacetic acid (for instance, when attempting to eliminate highly intractable tooth stains caused by tetracycline) in the tooth whitening composition. The peroxyacid may be included directly within the oxidizing composition (providing that transparency to light energy between about 350 and about 700 nanometers is maintained). Alternatively, the peroxyacid may be formed by combining two or more separate phases (one of which contains a peroxyacid precursor, such as glyceryl triacetate and a second that contains one of the oxidizing compounds listed above) prior to application to the tooth surface. Preferably, the peroxyacid is formed in situ, by contacting the tooth surface with a peroxyacid precursor prior to the application of an oxidizing compound; the peroxyacid is thus formed only on and within the stained tooth structure, where it is most beneficial to the tooth whitening process. Suitable peroxyacid precursors include, but are not limited to, glyceryl triacetate, acetylated amino acids, acetylsalicylic acid, and N,N,N',N'-tetraacetyl

ethylenediamine, vinyl acetate polymers and copolymers, acetylcholine, and other biologically acceptable acetylated compounds. A peroxyacid precursor may also be included in the accelerator composition of the present invention.

The oxidizing composition may be liquid, gel, or solid compositions transparent to the wavelength(s) of light capable of activating the photosensitizing agent at the tooth surface; light energy otherwise may also be attenuated by the film or layer of oxidizing compound between the actinic radiation source and the accelerator composition at the tooth enamel surface. Further, any commercially available peroxide-containing tooth whitening composition may be utilized in the compositions and methods of the present invention.

When the oxidizing compound is administered in a separate composition from the accelerator, the oxidizing compound may be present in the oxidizing composition in an amount of from about 1.0 % to about 40.0% by weight of the oxidizing composition. More particularly, the concentration of oxidizing compound in the oxidizing composition may range from about 10.0 % to about 20.0% by weight, about 20.0% to about 30.0% by weight, or about 30.0% to about 40.0% by weight. When the oxidizing compound and the accelerator are administered in one tooth whitening composition, the oxidizing compound may be present in the oxidizing composition in an amount of from about 0.1% to about 25.0% by weight of the tooth whitening composition. More particularly, the concentration of oxidizing compound in the tooth whitening composition may range from about 1.0 % to about 5.0% by weight, about 5.0% to about 15.0% by weight, or about 15.0% to about 25.0% by weight. An example of a suitable composition that is transparent to light energy between 380 and 500 nm is a 6% hydrogen peroxide gel with a pH adjusted to about 7.0 with an alkaline pH adjusting agent.

Another unexpected benefit of utilizing an oxidizing compound transparent to photosensitizing actinic radiation is that certain wavelengths of light seem to be absorbed by tooth chromogens in a manner that promotes their oxidation to a non-chromogenic state. Reflectance studies show that dentin and enamel transmit green light, reflect yellow/red light and absorb blue light. Although not wishing to be bound by any particular theory, light is absorbed by the molecules responsible for tooth discoloration; thus, tooth chromogens may act in a manner similar to that of photosensitizers. In particular, exposure to certain wavelengths may raise the energy state level of pi electrons carbonyl (C=O), double bond (C=C) and conjugated double bond (C=C--C=C) moieties, making them more susceptible to attack by active oxidizing species such as perhydroxyl anion (HOO--), peroxyacid anions (RCOOO--), and radical species such as hydroxyl radical (HO*) and perhydroxyl radical (HOO*). In order to destroy or solubilize chromogenic substances, the activation energy of the reaction between one of the above light-absorbing moieties and an active oxidizing species must be overcome; thus, light assisted chromogen attack leads to more efficient destruction of the molecular moieties responsible for the appearance of tooth discoloration by raising the energy state of electrons in specific chemical bonds within a light-absorbing molecule from a normal pi bonding orbital to a pi antibonding orbital. Whilst in the less stable pi antibonding orbital, a light absorbing double bond has considerable single bond character and is much more easily attacked by oxidizing compounds such as peroxides and peroxyacids. In theory, actinic light of a specific energy and wavelength, simply through the process described above, may utilize a tooth chromogen molecule as a photosensitizer in order to improve the efficacy of a given oxidative composition in contact with said tooth chromogen.

The accelerator of the present invention, whether present as a separate composition or mixed with the oxidizing compound in a tooth whitening composition, may include at least one of a photosensitive agent and an alkaline pH adjusting agent.

Photosensitizing agents useful as an accelerator in the present invention include any compounds capable of absorbing light energy at biologically acceptable wavelengths prescribed by the limits of safety for use in the oral cavity. In general, such wavelengths are from about 350 nanometers (nm) to about 700 nm, encompassing a portion of the UVA spectrum (300 to 400 nm) and most of the visible light spectrum (400 to 700 nm). Examples of compounds which may convert light energy to either heat or chemical energy, include semiconductor particles (particularly nanometer-scale titanium dioxide and zinc oxide), benzophenone derivatives, benzotriazole derivatives, diketones (such as camphorquinone and benzil), metal-ligand complexes (such as ferric potassium oxalate, manganese gluconate, and various metal-bisphosphonate chelates), phthalocyanin-metal complexes, and others. A specific example of a suitable photosensitizing accelerator composition is an aqueous dispersion of zinc oxide with particle sizes between 5 and 20 nanometers. Any molecule capable of absorbing a photon of light in the wavelength range of from about 350 nm to about 700 nm and subsequently converting the energy in said photon of light into the useful energy of oxidation either alone or in the presence of an auxilliary oxidizing compound, is contemplated to have utility in the practice of the present invention.

It is preferred that the inventive photosensitizers are of a molecular size, charge, pH and hydrophobicity/hydrophilicity to allow for effective penetration into the deeper structures of enamel and dentin. The more readily a photosensitizer penetrates the tooth structure, the more likely that, upon exposure of the photosensitizer to actinic radiation at the appropriate

wavelength and energy, said energy will be converted into oxidative activity at the site of, or in close proximity to, the chromogen itself. Photosensitizers having a molecular size, net charge, pH, and/or a hydrophobicity/hydrophilicity which prevent or limit penetration into deeper tooth structures are of utility in the practice of the present invention, but may be limited to the removal and/or destruction of chromogens located at the outer tooth surface (extrinsic stains).

Especially preferred photosensitizers belong to the general class of water-soluble metal-ligand complexes which absorb light in the range of from about 350 nm to about 700 nm, and can catalyze the destruction of tooth stain chromophores by generating free radical species in the presence of an oxidizer such as hydrogen peroxide. For the purposes of the present disclosure, the term "ligand" will mean an organic molecule capable of complexing or associating with a metal ion in aqueous solution, such that the reactivity, solubility, or any other physical property of said metal ion is changed. Such metal-ligand complexes are also known as metal-coordination complexes. Suitable metals ions include iron, manganese, copper, and other transition metal ions. For example, ferric chloride may be utilized as the photosensitive agent of the present invention. Various valence states may be used or may be present simultaneously. The metal ions may be present in saliva, plaque, or the acquired pellicle on the tooth surface. Metal ions may also contribute, through formation of oxides, to certain types of tooth stains. Suitable metal ion ligands include chelating agents capable of associating with the metal ions above in aqueous solution, resulting in a water-soluble metal-chelate complex that absorbs light between about 350 and 700 nm. Illustrative, but by no means limiting, examples of metal-coordination complexes are formed from the association of iron, manganese and copper with chelators such as ethylenediamine tetraacetic acid (EDTA), diethylenetriamine pentaacetic acid (DETPA), nitrilotriacetic acid (NTA), 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine

tetra(methylenephosphonic acid), diethylenetriamine penta(methylenephosphonic acid), and polyols such as sorbitol, xylitol, mannitol, maltitol, lactitol and other non-carboxylated polyhydroxy compounds more fully described in EP 443,651, such description being incorporated herein by reference. Any organic multi-dentate chelating agent capable of forming a photoabsorbing coordination complex with a metal ion can be presumed to have utility in the present inventive compositions for and methods of whitening stained teeth.

A number of the inventive catalytic metal-ligand complexes have an absorption spectrum that is pH-dependent; in general, such complexes will display a greater degree of absorption between 350 and 700 nm at a pH of greater than about 4.0, more particularly, at a pH of about 6.0 to about 12.0, light absorption in this range increasing with increasing pH. As the pH of the tooth surface is increased, for instance by use of accelerators described herein, such metal-ligand complexes become better photoabsorbers and thus more efficient at generating free radicals in the presence of an oxidizer and upon exposure to light energy. For instance, the aqueous complex formed between 1-hydroxyethylidene-1,1-diphosphonic acid and ferrous ions is virtually transparent to visible light at pH 3.0, but absorbs strongly in the spectral region between 350 and 500 nm as the pH is raised to 11.0. See FIG. 3.

In some cases, a photosensitizer precursor may be included directly within the oxidizing composition, where it does not readily absorb light in the visible region of the spectrum from 400 to 700 nm. However, upon contact with the tooth surface (when placed there with the oxidizing composition), the photosensitizer precursor may combine, for instance, with a metal ion such as iron present in saliva or found in the interstitial fluid of enamel and dentin, resulting in the formation, *in situ*, of an active photosensitizer capable of activating the oxidizing compound upon exposure to actinic radiation. As it is known that the level of certain metal ions, such as

iron, varies from one subject to another (and also from one tooth surface location to another), it is also possible to supplement the tooth surface with one or more metal ions, in order to assure sufficient and homogeneous metal-ligand levels prior to the application of a photosensitizer precursor. Obviously, only those compounds that are stable in a highly oxidative environment are suitable for inclusion directly in the oxidizing composition. An example of such a compound is 1-hydroxyethylidene-1,1-diphosphonic acid (available commercially under the trade name Dequest 2010 and sold as a 60% active solution by Monsanto Corporation, St. Louis, Mo.).

The ability of certain metal chelates to act as photosensitizers has been noted in the literature by various workers. For example, Van der Zee, et al ("Hydroxyl Radical Generation by a Light-Dependent Fenton Reaction" in Free Radical Biology & Medicine, Vol. 14, pp. 105-113, 1993) described the light-mediated conversion of Fe (III) to Fe (II) in the presence of a chelating agent and hydrogen peroxide. The reduction of Fe (III) chelates by light at 300 nanometers to yield Fe (II) was shown to proceed steadily over a period of about 30 minutes, with conversions to Fe (II) ranging from about 40% to about 80%, depending upon the particular chelating compound studied. The Fe (II) thus created initiated a Fenton-type degradation of the hydrogen peroxide, yielding hydroxyl radicals that were spin-trapped and detected by electron spin resonance (ESR). It was not suggested or implied by the authors that this photochemical reaction would have utility in the oxidation of chromophores, such as those found in a human tooth.

An alkaline pH adjusting agent of the present invention may be used as an accelerator to increase the pH of the oxidizing composition to a pH from about 6.0 to about 12.0, more particularly from about 7.0 to about 10.0. Any pharmaceutically acceptable alkaline pH adjusting agent may be used in the present invention including but not limited to sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, sodium

phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, polyethyleneimine, and other alkaline agents. The alkaline pH adjusting agent, when combined with the oxidizing compound either in formulation or upon application to the patient's teeth, raises the pH of the oxidizing compound. When the pH of the oxidizing compound, hydrogen peroxide for example, is increased, the oxidizing compound will degrade and generate free radicals more readily. As it degrades, the oxidizing compound will thus go through a degradation process conducive to destroying tooth stains, which accelerates the tooth whitening process. The ability of the accelerator composition to buffer the interface of the oxidizing compound and the tooth surface at a pH around 9 leads to more efficient degradation of hydrogen peroxide through non-enzymatic routes, as most peroxidase enzymes (including salivary peroxidase and catalase) have very low activities above a pH of around 8.0. Non-enzymatic hydrogen peroxide degradation methods produce intermediates that are known to be more conducive to chromogen (stain molecule) oxidation. Optionally, other means of reducing or eliminating peroxidase enzyme activity may be employed, and are known in the art. Such means include the addition of fluoride ion containing or releasing compounds, such as, for example, sodium fluoride, potassium fluoride, sodium monofluorophosphate, amine fluoride compounds, and other fluoride compouns. Other peroxidase enzyme inhibitors are known in the art and may include ethanol, for example.

The level of alkaline pH adjusting agent, when present, is from about 0.1% to about 90.0% by weight, more particularly, from about 1.0% to about 20.0% by weight, most particularly, from about 1.0% to about 10.0% by weight of the accelerator composition.

Acidic pH adjusting agents, such as citric acid, phosphoric acid, and others may also be used alone or in conjunction with an alkaline pH adjusting agent to obtain the desirable pH and to provide buffering capacity.

In addition to an accelerator, the accelerator composition may further include a performance enhancing adjuvant. The performance enhancing adjuvant may include at least one of a buffer, a surfactant, a thickener, a film forming ingredient, a penetration enhancer, and desensitizing agent.

A buffer may be added to the accelerator composition to stabilize the pH of the composition in storage and prior to use, and to increase the pH stability of the oxidizing compound at the tooth surface during the tooth whitening procedure. The buffer of the present invention may include any biologically or pharmaceutically acceptable buffer capable of stabilizing the pH of the composition during use in a range from about 6.0 to about 12.0. Suitable buffers may include but are not limited to glycine, glycine salts, ammonium phosphate, sodium phosphate, disodium phosphate, trisodium phosphate, potassium phosphate, dipotassium phosphate, tripotassium phosphate, ammonium phosphate, diammonium phosphate, ammonium citrate, diammonium citrate, sodium acid pyrophosphate, tetrasodium pyrophosphate, tetrapotsssium pyrophosphate, sodium trimetaphosphate, sodium bicarbonate, potassium bicarbonate, sodium acetate, boric acid salts, lactic acid salts, fumaric acid salts, and succinic acid salts.

In one embodiment, glycine is utilized as the buffer. Unlike most other buffering compounds, which are capable of stabilizing pH in only one pH range, glycine has two pH buffering or stabilizing regions. Fig. 5 illustrates the change in pH after addition of acidic pH

adjusting agent or an alkaline pH adjusting agent to glycine. As shown in Fig. 5, glycine exhibits excellent buffering action between pH 1.5 to 3.0 and between pH 9.0 to 13.0.

The concentration of the pH adjusting agent and buffer will depend on what is necessary to maintain a pH between about 6.0 and about 12.0 because the peroxide decomposes more rapidly the higher the pH, although the optimal pH may be between 7.8 and 9.0.

Further, the performance enhancing adjuvant of the present invention may optionally include one or more surfactants (surface active agents). Surfactants may be used to lower the surface tension of the compositions. Lowering of the surface tension allows for better wetting and spreading of the composition on the tooth surface. Some surfactants, such as zwitterionic and fluorinated surfactants, have been seen to increase the penetration of the present inventive compositions into the tooth structure. Useful surfactants include those identified in U.S. Pat. No. 5,279,816 and U.S. Pat. No. 5,302,375 each incorporated herein by reference in its entirety. Zwitterionic surfactants have positive and negative charges that significantly improve penetration of peroxide into the tooth. It is to be understood that additional useful surfactants will become apparent to those skilled in the art based upon the disclosure herein. The level of surfactant, when present, is from about 0.001% to about 10.0% by weight of the accelerator composition, and preferably from about 0.1% to about 1% by weight of the accelerator composition.

A thickener may also be added to the accelerator composition as a performance enhancing adjuvant to increase the contact time of the accelerator on the tooth surface. In one embodiment, the thickener provides coating properties for the accelerator by forming a film when applied to the teeth. Thickeners such as neutralized carboxypolymethylene and other polyacrylic acid polymers and copolymers, hydroxypropylcellulose and other cellulose ethers,

salts of poly(methyl vinyl ether-co-maleic anhydride), polyvinyl pyrrolidone (PVP), poly(vinylpyrrolidone-co-vinyl acetate), silicon dioxide, fumed silica, stearic acid esters, and others are found to have utility in the formulation of the oxidizing compositions and tooth whitening accelerator compositions. Polymers utilized as thickeners may also serve as film-forming agents that provide for even distribution of the accelerator composition over the tooth surface.. It is to be understood that additional useful thickeners will become apparent to those skilled in the art based upon the disclosure herein.

The level of thickener, when present, is highly dependent upon the type chosen, but in general is included in the composition at a concentration of from about 0.1 % to about 20.0 % by weight of the composition, and preferably at a concentration of from about 0.1% to about 5% by weight of the accelerator composition.

A penetration enhancer may also serve as a performance enhancing adjuvant in the present invention. As used herein, "penetration enhancer" shall be inclusive of all enhancers that increase the flux of a permeant, agent, or other molecule across the tooth or mucosal surface and is limited only by functionality. In other words, all cell envelope disordering compounds, solvents, steroidal detergents, bile salts, chelators, surfactants, non-surfactants, fatty acids, and any other chemical enhancement agents are intended to be included. Suitable solvents include water; diols, such as propylene glycol and glycerol; glycerine; mono-alcohols, such as ethanol, propanol, and higher alcohols; DMSO; dimethylformamide; N,N-dimethylacetamide; 2-pyrrolidone; N-(2-hydroxyethyl) pyrrolidone, N-methylpyrrolidone, 1-dodecylazacycloheptan-2-one and other n-substituted alkyl-azacycloalkyl-2-ones (azones) and the like. As used herein, "bile salts" means steroidal detergents that are the natural or synthetic salts of cholanic acid, e.g. the salts of cholic and deoxycholic acid or combinations of such salts, and the unionized acid

form is also included. Bile salt analogs having the same physical characteristics and that also function as permeation enhancers are also included in this definition.

The desensitizing agent of the compositions of the present invention may include potassium nitrate or a fluoride compound, for example. In one embodiment, the desensitizing agent includes sodium fluoride. The level of desensitizing agent, when present, is included in the composition at a concentration of from about 0.1 % to about 5.0 % by weight of the composition, and preferably at a concentration of from about 0.1% to about 1.0% by weight of the composition.

In addition to a performance enhancing adjuvant, the accelerator composition and/or the oxidizing composition may further include a carrier. Any carrier known in the art may also be included in the oxidizing composition and/or accelerator composition of the present invention. In one embodiment, the accelerator composition includes water as a carrier in an amount of from about 60.0% to about 99.99% by weight of the composition. More particularly, water may comprise from about 70.0% to about 95.0% by weight of the accelerator composition.

Flavorants may also be included in the accelerator composition in order to improve palatability and acceptance by the patient. Flavorants are generally known in the art and include, among others, spearmint, peppermint, anethole, menthol, citrus flavors, and vanilla. It may be desirable to provide within the composition an artificial sweetener selected from the group of sodium saccharin and potassium acesulfame. Sugars and sugar alcohols, such as sucrose, fructose, glucose, xylitol, maltitol, mannitol, sorbitol, and other mono-, di-, tri-, and higher monosaccharides may be used as sweeteners. For example, glycine may also serve as a sweetener and has the ability to mellow saltiness and bitterness of the pH adjusting agent. Both flavorants and sweeteners, when present, are each included at a level of from about 0.01% to

about 5.0% by weight of the composition. Other artificial sweeteners are contemplated to have utility in the practice of the present invention, limited only by their solubility and stability in the compositions.

In one embodiment, the accelerator composition is a composition comprising water, glycine, PVP, and potassium hydroxide. PVP is a thickener and adhesion-promoting agent that provides a sufficient thickness of film on the tooth surface in order to deliver a sufficient amount of the alkaline pH adjusting agent to raise the pH higher when the interface forms between the accelerator film and the oxidizing compound.

Other ingredients may also be added to the compositions of the present invention such as pyrophosphate salts, peroxide stabilizers, soluble and insoluble calcium compounds disclosed in U.S. Pat. No. 5,279,816 and U.S. Pat. No. 5,302,375. In addition, antimicrobial compounds may also be added to the compositions of the present invention in amounts sufficient to have an antimicrobial effect.

Table 1 provides several different embodiments of the accelerator compositions of the present invention. Formulation 4 below describes a composition useful for normalizing the level of metal-ligand photosensitizer at the tooth surface prior to placement of an oxidizing agent and subsequent exposure to light.

Table 1

Raw Material	% By Weight										
	1	2	3	4	5	6	7	8	9	10	11
Water	88.49	95.00	86.88	99.98	99.00	48.50	70.50	70.50	79.49	78.00	80.50
Glycine	7.51		7.51						7.51	7.50	7.50
NaOH	4.00										
KOH			5.61								2.0
KOH, 45%								3.33	3.00	4.50	
$(NH_4)_2PO_4$		5.00									
Dequest 2010				0.01	0.50	0.50	0.50	0.50			
Ferric chloride				0.01							
Carbopol					0.50	1.00	1.50	1.50			
PVP									10.00	10.00	10.00
K_2PO_4						50.00	12.50	27.50			
K_3PO_4							15.00				
pH	12.12	10.88	11.40	6.80	6.05	9.18	11.27	9.50	9.30	9.82	9.67

A light-activated tooth whitening method, in accordance with one embodiment of the invention, includes contacting the tooth enamel surface of a patient with a tooth whitening composition comprising an oxidizing compound and an accelerator, and, thereafter, exposing the tooth surface to light energy. Alternatively, a method of whitening teeth includes contacting the tooth enamel surface of a patient with an accelerator composition, then sequentially contacting the treated tooth surface with an oxidizing composition, and, thereafter, exposing the tooth surface to light energy. In a preferred embodiment, the light energy is capable of activating the oxidizing compounds at the tooth enamel surface. The preferred wavelengths of light in this embodiment include those between about 350 and about 700 nanometers, a more preferred embodiment include those between about 380 and about 550 nanometers with the most preferred wavelengths being between about 400 and about 505 nanometers. In yet another embodiment, a method of whitening teeth includes contacting the tooth enamel surface of a patient with an oxidizing composition, then sequentially contacting the treated tooth surface with an accelerator composition, and, thereafter, exposing the tooth surface to light energy.

Various modes of application of the inventive tooth whitening compositions are effective. Methods that allow for the accumulation or concentration of the photosensitizer within the acquired pellicle, enamel, and dentin (the three tooth structure primarily associated with the majority of tooth staining) are one of the preferred embodiments. This may be accomplished by contacting the stained tooth surface with the photosensitizer prior to contacting the same stained tooth surface with the oxidizing composition. In this way, the photosensitizer is able to penetrate into the tooth structure, thus being present at the site of the tooth chromogen(s) prior to contact with the oxidizing composition and prior to exposure to the actinic radiation source.

As such, one embodiment of the light-activated tooth whitening method of the present invention, includes contacting the tooth enamel surface with an accelerator composition comprising a photosensitive agent, then contacting the photosensitizer-treated tooth surface with the oxidizing compound, and, thereafter, exposing the tooth surface to light energy that activates the oxidizing compounds at the tooth enamel surface.

Another light-activated tooth whitening method, in accordance with another embodiment of the invention includes contacting the tooth enamel surface with tooth whitening composition comprising an oxidizing compound and a photosensitizer precursor, whereby said precursor is seen to absorb actinic radiation in the range of 350 to 750 nm only after contact with said tooth surface. Once the photosensitizer precursor becomes light absorbent, the tooth surface is exposed to light energy capable of activating the now absorbent photosensitizer, which in turn activates the oxidizing compound at the tooth surface to whiten the tooth.

A further light-activated tooth whitening method, in accordance with another embodiment of the invention includes contacting the tooth enamel surface with an oxidizing compound and thereafter exposing said tooth enamel surface to actinic radiation corresponding

to a tooth chromogen molecule absorption wavelength. The preferred wavelengths of light in this embodiment include those between about 350 and about 700 nanometers, a more preferred embodiment include those between about 380 and about 550 nanometers with the most preferred wavelengths being between about 400 and about 505 nanometers. As in all of the methods described above, the oxidizing composition must be transparent to the actinic radiation utilized in order to allow the wavelength-specific light energy to reach the tooth surface and underlying structure.

Yet another light-activated tooth whitening method, in accordance with another embodiment of the invention includes contacting the tooth enamel surface with a peroxyacid precursor prior to contacting said tooth enamel surface with an oxidizing compound and subsequently exposing to actinic radiation as described above. The peroxyacid precursor may be placed on the tooth surface together with or separately from a photosensitizer.

Stained teeth may be treated individually, for instance, by directing the light to a single tooth surface by means of a fiber optic light guide. In this manner, several stained teeth are exposed to light in sequence, the dentist or hygienist moving the light guide from tooth to tooth during the procedure. Alternatively, all of the stained teeth may be exposed to light simultaneously either by direct illumination from a light source shaped substantially like the dental arch or by indirect illumination from a light guide or device that is capable of illuminating all of the front teeth at once.

One such device for the simultaneous and uniform illumination of at least eight central teeth in both the upper and lower arches is illustrated in FIG. 1. This preferred embodiment has three linear optical outputs 11, 12, and 13 precisely positioned on three front (patient facing) surfaces 1, 2, and 3. In a more preferred six bar embodiment, two three bar devices are stacked

one on the other resulting in six optical outputs on the front patient facing surfaces as illustrated in FIG. 2.

Although FIGS. 1 and 2 illustrate embodiments having 3 outputs and 6 outputs, respectively, it is contemplated that the device may have any number of outputs or emitters, from one to a high multiple of outputs. Each output consisting of an individual fiber or fiber bundle that ultimately is connected to a light source. Embodiments having 3 or 6 outputs may achieve fairly uniform illumination of the eight or more central teeth without excessive manufacturing problems or costs. More than six outputs, of course are feasible and may in fact be beneficial in terms of uniformity of illumination.

The front surfaces of the device are positioned to give an output configuration such that the combined beams from each optical output converge to illuminate at least the eight central teeth in both the upper and lower arches or the area from the incisors to the first pre-molars in each half arch, a total area of about 10.4 cm^2 in the average male. Although depicted in FIG. 1 as linear in form, these outputs may be of any shape, e.g., circular, triangular or linear. Linear forms are preferred. The preferred embodiments have six linear outputs, each output having a length to width ratio of about 16$\pm$20%--i.e., ratios of 12.8 to 19.2. In the most preferred embodiment, 80% of the light projected from the outputs onto the 8 upper and lower central teeth is within an area between about 0.9 and about 1.5 inches wide, the approximate distance from the top of the enamel of the top teeth to the bottom of the enamel of the bottom teeth. Each optical output preferably is connected to a distal light source by two glass or plastic fiber optic bundles which originate at the distal light source, enter the device through a socket 20 and terminate at the trifurcated linear output window. Non-uniformity in fiber transmission is generally observed to

be minor in the absence of actual breaks in the fibers. Variation in optical output from point to point at the surface of each output or emitter should be no more than about ±10%.

A number of different sources of actinic radiation have been shown to have utility in the practice of the present invention. In general, any light source capable of emitting actinic radiation in the wavelength range necessary to activate either the inventive photosensitizer(s) or the oxidizing compound or otherwise raise the energy state of tooth chromogens, is contemplated to have utility in the practice of this invention. In particular, light sources capable of emitting actinic radiation that is both biologically safe and effective are preferred, especially those sources which emit limited amounts of infrared light (700 nm and above). Infrared light more readily penetrates the tooth structure and may cause an excessive temperature rise in pulpal tissue. In one embodiment, light sources (combined with filters) emitting only those wavelengths necessary for the activation of the inventive photosensitizer and/or the activation of a tooth stain chromophores are used in the process of whitening teeth with the inventive compositions. It is generally accepted that a pulpal temperature rise of more than 5.5° C for a significant period of time can be irreversibly damaging to the tooth structure.

Light sources which emit actinic radiation in the wavelength range from about 350 nanometers to about 700 nanometers may be used, in that both the photosensitizers and the oxidizing compound described herein and the tooth chromogen molecules responsible for tooth staining absorb primarily in this region of the spectrum. Particularly, light sources which emit actinic radiation in the wavelength ranges from about 400 and about 505 nanometers may be used. Output uniformity should be about ± 10% over the area of the beam once transmitted through a glass or plastic fiber to the optical output which may be placed in front of a patient's teeth. Although there are no limitations on the input and length dimensions of such a fiber, one

of about 10 millimeters in diameter and 3 meters in length is preferred. Such energy may be provided by a source which generates a continuous electromagnetic spectrum filtered to the preferred wavelengths with a variation of no more than about ±10%, or by a source which generates an emission line spectrum, or a combination of both. Suitable lamps which emit actinic radiation in the preferred range of wavelengths include linear flash lamps, tungsten halogen, metal halide, Xenon short arc, Mercury short arc, Mercury Xenon short arc, Argon plasma arc, and Argon short arc lamps, among others. The output of two Mejiro BMH 250 watt metal halide lamps filtered through dichroic filters to between about 400 and 505 nanometers meet these criteria, for example.

A preferred light source is a plasma arc lamp. The most preferred light sources are the BriteSmile 2000™ and BriteSmile 3000™ light sources, plasma arc lamps. The BriteSmile 2000™ is an integrated light source and delivery system in which a fixed light delivery head delivers energy efficient light of selected wavelengths to the teeth. The light from the lamp is conducted via a fiber optic cable to the delivery head that positions and distributes the light to obtain a maximum efficiency at the work site. The BriteSmile 2000™ light source comprises a lamp module, control panel, delivery system, and a support structure. The BriteSmile 3000™ light source has a mobile support structure and a key card system for its access.

The lamp module, of both the BriteSmile 2000™ and BriteSmile 3000™, comprise one or more metal halide lamps with integrated power supplies. In a preferred embodiment, the output is filtered to provide an efficient source of visible blue light in the 400-550 nm range. In a more preferred embodiment, light is filtered to be in the 400-505 nm range.

The control panel of the BriteSmile 2000™ and BriteSmile 3000™ comprise a membrane switch to activate and set parameters and an alphanumeric display with visual and

audio indicators to communicate information to an operator. The delivery system may comprise a flexible arm with an integrated optical fiber delivery system and a light delivery head which is permanently mounted to a support structure. The support structure provides the mounting structure for the lamp modules, control panel, and light delivery system. The support structure of the BriteSmile 2000™ also provides a self-contained water system and a site for hookups to centralized air and suction.

Other light sources are described in United States Patent No. 6,416,319 and United States Provisional Patent Application Serial No. 60/158,499 which are herein incorporated by reference. Any tooth whitening method can be used in the method of the invention, so long as the effectiveness is sufficiently good to provide for substantial tooth whitening in less than about 120 minutes. Preferred tooth whitening procedures are capable of substantially whitening a client's teeth in less than 120 minutes, more preferred tooth whitening procedures are capable of substantially whitening a client's teeth in less than about 90 minutes, and most preferred tooth whitening procedures are capable of substantially whitening a client's teeth in less than about 60 minutes. Thus, any composition and/or procedure for whitening teeth can be used in the tooth whitening modules of the invention provided that substantial whitening of each client's teeth is achieved in less than about 120 minutes.

Whether illumination of the stained teeth is performed individually or as a whole, the light emerging from a direct or indirect source may be continuous ("on" the entire procedure), interrupted continuous (primary "on" with short rest interruptions), pulsed ("on" and "off" in a predetermined timed sequence and intensity), or a combination of continuous, interrupted continuous and pulse. In one embodiment from about 10 to about 200 milliWatt/cm^2 of light is applied continuously to the front surface of the teeth for a total period of time from about 10 to

about 90 minutes. In another embodiment from about 100 to about 160 milliWatt/cm^2 of light is applied continuously or continuously with short interruptions to the front surface of the teeth for a period of time from about 10 minutes to about 30 minutes followed by an interruption or "off" period of about 1 to 10 minutes, with the cycle repeated for a total time of approximately 40-60 minutes. In one embodiment, the oxidizing compound is first applied to the tooth enamel surface for a period of 20 minutes of light activation. The oxidizing compound is then aspirated or suctioned off the teeth and the accelerator composition is applied to the tooth enamel surface followed by application of the oxidizing compound for another 20 minute period of light activation. The accelerator composition and the oxidizing compound are then aspirated or suctioned off and step two is repeated for a total of three 20 minute periods. In one envisioned embodiment of the invention a feed-back mechanism based on reflectance would be used to monitor bleaching efficiency and regulate the total amount of actinic radiation applied. In all embodiments of the invention the positioning of the light source affects the energy density applied to the teeth as power density decreases with distance. The preferred placement of the light source will vary depending on the precise nature of the device. For the device described above, the preferred distance for placement of the device is from directly in front of the surface of the teeth up to about 2.0 inches in front of the surface of the teeth (when measured from the middle of the light source to the central tooth). In another embodiment, the light source is placed inside the oral cavity either in direct contact with the teeth or slightly spaced therefrom.

Other pre-treatment and post-treatment steps may also accompany the inventive methods of the present invention. For example, a barrier material may be applied to the gingival area of the gums prior to application of the oxidizing compound and accelerator.

One embodiment of the present invention includes each of the following steps:

(1) A barrier material to protect the gums from the oxidizing agent (supplied by BriteSmile, Inc., Walnut Creek, CA) is first applied to the upper first and second premolar gingival area starting at the gum line and tooth junction (actually contacting the enamel) and then cured for three seconds. The barrier material should be thick enough so that no pink gingival tissue is exposed. For every inch of isolation coverage, a standard curing light may be be used for no more than three seconds per any given spot to solidify the barrier material. The application of the barrier material is continued over the entire upper arch and then repeated for the lower arch.

(2) A masking cream (supplied by BriteSmile, Inc., Walnut Creek, CA) is then applied on both arches to any exposed lip areas and other mucosal tissue and on the outside of the cheek retractor to protect any exposed areas from excess illumination.

(3) The oxidizing composition is applied to the teeth 1 to 2 mm thick and any excess saliva is suctioned if necessary. The light source is positioned in front of the patient's teeth and activated for a period of approximately 20 minutes. After 20 minutes, the light source is removed from the patient's teeth and the oxidizing composition is suctioned from the patient's teeth.

(4) Prior to a second application of the oxidizing composition, an accelerator composition is swabbed onto the teeth to thoroughly moisten all tooth surfaces with a thin film of the accelerator composition from the swab.

(5) The second application of the oxidizing composition and any additional masking cream, as needed, are applied in the manner provided above. The light source is repositioned and activated for another approximately 20 minutes. After 20 minutes, the light source is

removed from the patient's teeth and the oxidizing composition and the accelerator composition are suctioned from the patient's teeth.

(6) Step 4 with a second application of the accelerator composition is repeated.

(7) The third application of the oxidizing composition is applied in the manner provided above. The light source is repositioned and activated for another approximately 20 minutes. After 20 minutes, the light source is removed from the patient's teeth and the oxidizing composition and the accelerator composition are suctioned from the patient's teeth.

(8) Once the procedure is finished, excess materials are removed from the patient, for example, cotton rolls, isolation material, optic positioner, excess barrier material, and cheek retractors. The teeth are then flushed thoroughly with water.

(9) If the patient experienced any discomfort during the treatment, or in the case of a young adult client, a neutral sodium fluoride treatment utilizing a white foam or clear neutral sodium fluoride may be administered.

Young adult patients may require only two 20-minute sessions to achieve their natural whiteness. Further, after the second session, the patient's teeth may be checked to determine if the third session is necessary.

Trays containing all of the components necessary to perform a single tooth whitening method may be prepared in advance (pre-pack) or just prior to the procedure. Some or all of the components may be disposable. In one embodiment, the tooth whitening trays comprise the following components: sterilizer bag, fiber-optic positioner, pre-whitening toothbrush, pre-whitening tooth paste, cheek retractor, oral napkin, syringe tips, examination/screening mirror, dental explorer, headrest cover, aspirator tip, client (patient) bib, saliva ejector, syringe tip cover, cotton rolls, gingival isolation material, mucosal isolation material (sunblock), accelerator

composition and oxidizing composition. The accelerator composition and oxidizing composition may be stored separately from the pre-pack components. In a preferred embodiment of the invention, all of the tray materials are disposable and the tray materials are disposed of after use.

The following examples set forth preferred embodiments of the invention. These embodiments are merely illustrative and are not intended to, and should not be construed to, limit the claimed invention in any way.

EXAMPLE I

In order to determine the ability of the inventive compositions to eliminate tooth stain, a preliminary in vitro study on stained bovine enamel was performed. Squares of dental enamel 4 mm on a side were cut, using a diamond-cutting disk, from bovine permanent incisors. Using a mold, the enamel squares were embedded in clear polyester casting resin (NTCOL Crafts Inc., Redlands, Calif.) to provide 1.5 cm square blocks with the labial surface exposed. The top surface of the polyester blocks was ground flush with the leveled labial surface of the enamel squares by means of a dental model trimmer. The surface was then smoothed by hand sanding on 400-grit emery paper using water as the lubricant until all grinding marks were removed. Finally, the top surface of the blocks was hand polished to a mirror finish using a water slurry of GK1072 calcined kaolin (median particle size=1.2 microns) on a cotton cloth. The finished specimens were examined under a dissecting microscope and were discarded if they had surface imperfections.

In preparation for the formation of artificial stained pellicle on the enamel, the specimens were etched for 60 seconds in 0.2M HCl followed by a 30-second immersion in a saturated solution of sodium carbonate. A final etch was performed with 1% phytic acid for 60 seconds, then the specimens were rinsed with deionized water and attached to the staining apparatus.

The pellicle staining apparatus was constructed to provide alternate immersion into the staining broth and air-drying of the specimens. The apparatus consisted of an aluminum platform base which supported a Teflon rod (3/4 inch in diameter) connected to an electric motor, which by means of a speed reduction box, rotated the rod at a constant rate of 1.5 rpm. Threaded screw holes were spaced at regular intervals along the length of the rod. The tooth specimens were attached to the rod by first gluing the head of a plastic screw to the back of a specimen. The screw is then tightened within a screw hole in the rod. Beneath the rod was a removable, 300-ml capacity trough, which held the pellicle, staining broth.

The pellicle staining broth was prepared by adding 1.02 grams of instant coffee, 1.02 grams of instant tea, and 0.75 grams of gastric mucin (Nutritional Biochemicals Corp., Cleveland Ohio 44128) to 250 ml of sterilized trypticase soy broth. Approximately 50 ml of a 24-hour Micrococcus luteus culture was also added to the stain broth. The apparatus, with the enamel specimens attached and the staining broth in the trough was then placed in an incubator at 370°C with the specimens rotating continuously through the staining broth and air. The staining broth was replaced once every 24 hours for ten consecutive days. With each broth change the trough and specimens were rinsed and brushed with deionized water to remove any loose deposits. On the eleventh day the staining broth as modified by the addition of 0.03 grams of $FeCl_3 \cdot 6H_2O$, and this was continued with daily broth changes until the stained pellicle film on the specimens was sufficiently dark. Then the specimens were removed from the staining broth, brushed thoroughly with deionized water, and refrigerated in a humidor until used.

Absorbance measurements over the entire visible spectrum were obtained using the CIELAB color scale (Commission International de L'Eclairage, Recommendations on uniform color spaces, color difference equations, and psychometric color terms, Supplement 2 to CIE

publication 15 (E-13.1) 1971 (TC-1.3), 1978, Paris: Beaurea Central de la CIE, 1978). The CIELAB color scale evaluates color in terms of three axes of a color sphere, called L, a, and b. The "L" value is the axis in the color sphere which relates lightness and darkness on a scale from 0 (black) to 100 (white). The "a" value is the axis which relates color on a yellow to blue scale, with a 0 value in the center of the sphere, positive values toward the yellow, and negative yellow toward the blue. The "b" value is the axis which relates color on a red to green scale, with a 0 value in the center of the sphere, positive values toward the red, and negative values toward the green.

The stained enamel specimens were allowed to air-dry at room temperature for at least one hour before absorbance measurements were made. Measurements were conducted by aligning the center of a 4-mm square segment of stained enamel directly over the 3-mm aperture of the Minolta spectrophotometer. An average of 3 absorbance readings using the L*a*b* factors were taken for each specimen.

The difference between the pre-treatment (baseline) and post-treatment readings for each color factor (L*, a*, and b*) represented the ability of a test solution to eliminate chromogens from the stained teeth.

The overall change in color of stained pellicle was calculated using the CIELAB equation

$$\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$$

A "Corrected ΔE" value was calculated by eliminating from the above formulation the contribution of any positive Δa or Δb values (positive Δa and Δb values are changes in tooth color in the opposite direction from zero, and hence construed to add color, rather than remove it).

The following oxidizing composition was prepared, which contained approximately 15% by weight hydrogen peroxide and 1 percent by weight of the photosensitizer precursor 1-hydroxyethylidene-1,1-diphosphonic acid (Dequest 2010, Monsanto Corp., St. Louis, Mo.). Highly purified water (18.2 megaohm, filtered through a 0.2 micron filter) was utilized in order to maintain good stability of the composition during storage. The composition was thickened with a carboxypolymethylene polymer (Carbopol 974P, B. F. Goodrich Co., Cleveland, Ohio) to the consistency of a light, non-runny gel. Glycerin was added in a small percentage as a humectant and stabilizer (as a free radical scavenger), and the Carbopol 947P was neutralized to a pH of 5.00 with ammonium hydroxide, resulting in the formation of a transparent and thixotropic gel.

Formulation 12

Ingredient	Percentage
Distilled water	49.400
1-hydroxyethylidene-1,1-diphosphonic acid	1.000
Glycerin 99.7%	5.000
Hydrogen peroxide 35%	42.900
Carbopol 974P	1.700
Ammonium hydroxide 29%	to pH 5.5
TOTAL	100.000

The above composition was prepared in a plastic mixing chamber by combining, under agitation with a Teflon-coated mixing paddle until a clear solution was obtained, the distilled water, the 1-hydroxyethylidene-1,1-diphosphonic acid, and the glycerin. The Carbopol 974P was then sifted slowly into the vortex created by the mixing paddle and allowed to mix until a homogeneous slurry of the polymer was obtained. Finally, the ammonium hydroxide was added in a constant, dropwise fashion over a period of about 5 minutes until thickening and clarification

of the slurry occurred. A pH probe was inserted periodically and the ammonium hydroxide addition proceeded until a pH of exactly 5.00 was obtained. The resulting gel contained 15% by weight hydrogen peroxide, and was highly transparent and thixotropic (non-slumping) in character.

Each stained bovine enamel slab was coated with a 1-2 mm film of the composition in Formula 12 above for a specified period of time and exposed to actinic radiation from one of several light sources. Table 2 below shows some comparative results obtained by exposing gel-treated enamel slabs to either Argon plasma arc (AR) or tungsten halogen (TH) light sources. This particular protocol called for the fiber optic light guide to be placed 5 mm from the surface of the enamel during light exposures. The energy of each pulse was adjusted with a power density meter prior to each exposure regimen and measured again after each regimen to verify consistent output of the light source over the duration of the test. The results are listed in Table 2 below:

TABLE 2

Bovine Tooth #	Light Source	Total Gel Contact Time	Number of Pulses	Energy/Pulse (Joules)	Corrected Delta E*
B311	None	30 min	0	0.00	12.76
B388	AR	None	30	1.66	1.41
B277	AR	30 min	30	1.66	29.28
B214	AR	30 min	30	3.35	29.75
B283	AR	10 min	10	3.29	18.62
B147	AR	10 min	10	4.90	25.98
B401	AR	10 min	30	4.97	32.18
B211	AR	5 min	15	4.84	20.05
B213	AR	5 min	30	4.93	31.02
B35	TH	5 min	15	1.29	12.88
B35	TH	5 min	15	1.29	19.39
B35	TH	5 min	15	1.29	20.01
B35	TH	5 min	15	1.29	23.61
B35	TH	5 min	15	1.29	25.35
B35	TH	5 min	15	1.29	26.41

*Elimination of positive Δa and Δb values from calculation

The data in Table 2 demonstrates that:

(1) In the in vitro model described, exposure of bovine enamel slabs, contacted with the inventive gel composition above, to pulsed actinic radiation from a Argon plasma arc light source resulted in significantly reduced tooth stain as compared to slabs treated either with just gel alone (and not exposed to the light source) or light source exposure only (no gel).

(2) Six sequential treatments (over 30 minutes) of a single stained bovine enamel slab (B35) with gel and concurrent exposure of said slab to pulsed actinic radiation from a tungsten halogen light source (5 minute exposure periods) resulted in an increasing level of tooth stain removal over the period of the test. The result was significantly lighter in color than that

achieved in tooth number B311, which was also in contact with the inventive gel composition, but did not get exposed to a light source.

EXAMPLE II

A comparative study of light transmission through various light and/or heat activated tooth whitening gels was undertaken. Spectral energy curves were generated using an Ocean Optics spectrometer with a 50 micron fiber for gather emission data. Light transmission through a glass microscope slide was used as a control and the test consisted of coating the slide with a 1-2 mm thick layer of each tooth whitening gel and illuminating with a metal halide light source connected to an 8 mm glass fiber optic light guide. The light was filtered through a 505 nm short pass filter (only wavelengths less than 505 nm pass through) prior to entering the light guide. The spectrometer's fiber optic probe was placed against the opposite side of the slide from the gel in order to detect the wavelengths of light allowed to pass through the gel on the slide. The spectral curves of FIGS. 4 A-E clearly demonstrate the degree of light attenuation caused by all of the commercially available compositions: FIG. 4A-Control; FIG. 4B-Inventive Example I; FIG. 4C-Shofu Hi-Lite; FIG. 4D-QuasarBrite; FIG. E-Opalescence Xtra.

The attenuation of power density, measured in mW/cm^2, was determined for the same four compositions by again placing a 1-2 mm layer of each gel or paste on a glass microscope slide and placing the slide/gel assembly in the path between the light source and the detector well of the power density meter. Due to the depth and shade of the detector well, the slide was 7 mm above the actual detector surface, rather than directly in contact with it. The power density was recorded at the beginning (B) and at the end of a 60 minute light exposure (E). The power density without slide or gel in the light path was adjusted to 175 mW/cm^2. The results are shown in Table 3 below.

TABLE 3

Composition	U.S. Pat. No.	Energy Density (m W/cm.sup.2)
Control (slide only)	--	165
Example I (B) + (E)	--	160
& So Shofu Hi-Lite (B)	5,032,178	25
Shofu Hi-Lite (E)	5,032,178	50
QuasarBrite (B)	5,240,415	110
QuasarBrite (E)	5,249,415	111
Opalescence Xtra (B)	5,785,527	65
Opalescence Xtra (E)	5,785,527	94

EXAMPLE III

Another transparent hydrogen peroxide gel was prepared that had a lower concentration of oxidizer (3% by weight of H_2O_2), but at a pH of 7.0 and a much higher viscosity (approximately 1,000,000 cps). The gel below was prepared in accordance with the procedure in Example I, except that a Kynar coated Ross Double Planetary vacuum mixer (Charles Ross & Sons, Hauppauge, N.Y.) was used to handle the elevated viscosity achieved during and after neutralization with the ammonium hydroxide. Sodium stannate was added as an additional stabilizer for the hydrogen peroxide.

Formulation 13

Ingredient	Percentage
Distilled water	81.010
Glycerin 99.7%	5.000
1-hydroxyethylidene-1,1-diphosphonic acid	0.400
Sodium stannate	0.015
Hydrogen peroxide 35%	8.570
Carbopol 974P	5.000
Ammonium hydroxide 29%	to pH 7.0
TOTAL	100.000

The ability of the 3% hydrogen peroxide gel, transparent to visible light between the wavelengths of 380 and 700 nanometers, is demonstrated in Table 4 below.

TABLE 4

Bovine Tooth #	Oxidizing Gel	Time Period	Light Source	Wavelength Range (nm)	Pulses/ Period	Power Density (mW/cm2)	Energy/ Pulse (Joules)	Delta E*
B388	Example II	5 min	AR	380-505	15		4.84	19.67
B388	Example II	5 min	AR	380-505	15		4.84	29.43
B388	Example II	5 min	AR	380-505	15		4.84	32.74
B365	Example II	5 min	None	--	0		0	3.41
B365	Example II	5 min	None	--	0		0	4.23
B365	Example II	5 min	None	--	0		0	5.78
B365	Example II	5 min	AR	380-505	15		4.84	23.49
B365	Example II	5 min	AR	380-505	15		4.84	30.27
B367	Example I	30 min	TH	400-520	Contin-uous	250		32.26

*Elimination of positive Δa and Δb values from calculation.

EXAMPLE IV

Extracted human teeth (HE) that were non-carious and free of amalgam or resin-based restorative materials were utilized to study the ability of the inventive compositions to eliminate

the strains from human enamel and dentin. The teeth were coated with a 1-2 mm thick film of an oxidizing gel and irradiated according to the regimens shown in Table 5 below. The resulting change in tooth color (Δ Shades) was recorded as the number of VITA® shade difference between the original baseline VITA® shade value and the final VITA® shade value.

TABLE 5

Tooth #	Gel	Light Source	Exposure Time (min)	Pulses/ Minute	Joules/ Pulse	Shade (Initial)	Shade (Final)	Δ Shade
HE2	Example I	AR	30	1	4.84	B4	C2	6
HE3	Example I	AR	30	1	4.84	A4	A3.5	3
HE4	Example I	AR	30	1	4.84	A3	B2	6
HE5	Example I	AR	30	1	4.84	B3	D4	3
HE6	Example I	AR	30	1	4.84	B3	B2	8
HE7	Example I	AR	30	1	4.84	A3	A1	7
HE8	Example I	AR	30	1	4.84	A3.5	A2	7
HE9	Example I	AR	30	1	4.84	A3	A1	7
HE10	Example I	AR	30	1	4.84	A4	A3.5	6
HE11	Example I	AR	30	1	4.84	A3.5	A2	7
HE12	Example I	AR	30	2	4.84	A3.5	A2	7
HE13	Example I	AR	30	2	4.84	B3	B2	8
HE14	Example I	AR	30	2	4.84	A3.5	B2	9
HE15	Example I	AR	30	2	4.84	A4	A1	13
HE16	Example I	AR	30	2	4.84	B4	B1	12
HE17	Example I	AR	30	1	1.64	A3	A2	4
HE18	Example I	AR	30	1	1.64	B4	B2	10
HE19	Example I	AR	30	1	1.64	C4	D3	6
HE20	Example I	AR	30	1	1.64	B3	A2	6
HE21	Example I	AR	30	1	1.64	B3	B2	8
HE22	Example I	No light	30	0	0	B3	A2	2
HE23	Example I	No light	30	0	0	A3	A2	4
HE24	Example I	No light	30	0	0	B3	D4	3
HE25	Example I	No light	30	0	0	D3	B2	7

Tooth #	Gel	Light Source	Exposure Time (min)	Pulses/ Minute	Joules/ Pulse	Shade (Initial)	Shade (Final)	Δ Shade
HE26	Example I	No light	30	0	0	B3	A2	6
HE27	Example I	Tungsten Halogen	60	Continuous	250 mW/cm^2	B3	A1	9

EXAMPLE V

Human extracted teeth were whitened as follows by applying a 1-2 mm thick film of gel on the enamel surface and exposing the same surface to varying power densities from a metal halide light source with a 505 nm short pass internal filter. Comparisons were done to two controls, one of which was Gel exposure only (no light) and light exposure only (no Gel). Exposure regimens, consisting of gel application (except in the case of light only/no Gel), followed by 20 minutes of continuous light exposure, were repeated three times (3 x 20 minutes).

TABLE 6

Tooth #	Gel	Light Source	Power Density (mW/cm^2)	Filter	Test Duration	Initial Shade	Final Shade	Δ Shade
HE101	Example I	MH	250	505	3x20 min	A3.5	A1	7
HE102	Example I	MH	250	505	3x20 min	B4	A2	8
HE103	Example I	MH	175	505	3x20 min	A3	B1+	8
HE104	Example I	MH	175	505	3x20 min	A4	B2	12
HE105	Example I	MH	175	505	3x20 min	B3	B2	8
HE106	Example I	MH	175	505	3x20 min	A3	B1+	8
HE107	Example I	MH	175	505	3x20 min	A4	A2	10
HE108	Example I	No light			3x20 min	A3.5	A3	3
HE109	Example I	No light			3x20 min	A4	D3	5
HE110	Example I	No light			3x20 min	A3.5	A3.5	0
HE111	Example I	No light			3x20 min	A4	A3	6
HE112	Example I	No light			3x20 min	A4	A3.5	3
HE113	None	MH	175	505	3x20 min	A3	A3	0

Tooth #	Gel	Light Source	Power Density (mW/cm^2)	Filter	Test Duration	Initial Shade	Final Shade	Δ Shade
HE114	None	MH	175	505	3x20 min	A4	A4	0
HE115	None	MH	175	505	3x20 min	A3.5	A3	3
HI116	None	MH	175	505	3x20 min	B3	B3	0

EXAMPLE VI

A pulpal chamber of an endo-tooth in a cooperative and informed patient was wired using a thermal probe and thermo-conducting paste. Pulpal temperatures were measuring during an actual whitening procedure, in which the illumination was supplied using the currently available Union Broach Illuminator and the device described in the instant application used at the most preferred wavelengths of 400 to 505 nanometers. Measurements of the energy densities at the tooth surface showed comparable energy densities for each device (230 milliwatts/cm^2 for the Union Broach Illuminator and 200 milliwatts/cm^2 for the device described in the instant application, respectively). The results are shown below in Table 7.

Illumination using the device described in the instant application in the preferred wavelength range from about 400 to 505 nanometers raised pulpal chamber temperature less than did the Union Broach device. In this experiment, temperatures rose to a maximum by twenty minutes and were then stable. In contrast to the temperature rise seen with the Union Broach device, at no time did the temperature using the device disclosed in the instant application rise above the 5.5° C which could result in thermally induced pulpitis if maintained for a significant period of time. The temperature changes seen are likely to be greater than those seen with vital teeth as endo-teeth have no blood supply to provide additional cooling.

TABLE 7

Temperature Rise (deg. C from ambient)		
Time (min.)	Union Broach	BriteSmile 2000
5	4	2.9
10	8	4.5
15	9	5.3
20	9	4.2
25	9.5	4.5
30	9	4.3

EXAMPLE VII

In order to determine whether increases in the efficacy of light activated whitening system may be accomplished without increasing the concentration of hydrogen peroxide, an accelerator composition was applied to a patient's teeth just prior to second and third applications of the oxidizing compound (15% hydrogen peroxide, pH 6.5) to a patient's teeth. The accelerator composition utilized was a slightly viscous liquid comprising deionized water, an alkaline pH-adjusting agent (potassium hydroxide), a thickener/film former (PVP), and a buffering agent (glycine). The overall pH of the accelerator liquid as applied to the tooth surface was approximately 9.8.

Just prior to the second and third oxidizing compound treatment steps, the accelerator composition was applied to the teeth with a pre-wetted, unit-dosed swab device. The tooth surface was "primed" with the accelerator composition just prior to the placement of the oxidizing composition for the second and third 20-minute cycles.

Prior to treatment, patients were screened using normal methods that are standard at BriteSmile, Inc. centers and 100 patients A3 and darker were selected for the enhanced treatment. Pre- and post-treatment shades were taken using the classic VITA® PAN shade guide

ordered in value mode according to the manufacturers instructions. An experienced dental staff at the center that has conducted thousands of whitening procedures recorded the before and after shade values.

The results of the procedure are as follows:

Average Pre-treat shade	11.5 (+/-2.3)
Average Final shade	2.3 (+/-1.7)
Average Shade change	9.3
Average success factor[1]	91%

FIG. 6 shows a histogram of the pre-treatment shades (bars A3 and darker) vs. the post-treatment shades (bars C1 and lighter) for this clinical sample. The clean separation was apparent. One of the important measures of whitening success was moving the patient to the top of the whitening scale. A "whitening success factor" may be defined as the percent of the maximum possible change between the starting shade and whitest shade (B1).

Whitening success factor (expressed as a %) =

(Starting shade - Final shade)/ (Starting shade – 1)

The "success factor" measures the average percentage of the distance from the starting shade to B1 that was achieved.

FIG. 7 shows the whitening success factors for each of the nine starting shades. The average success factor in the total sample was 91%. By comparison 96% of whitening cases in this survey that started at D3 or lighter achieved a success factor or 100% as a final result; that is, the endpoint was B1. This also suggests that the general success rate for achieving B1 for starting shades D3 or lighter should be very high.

Laboratory studies indicated that the increased efficacy observed in this methodology resulted from the increased pH at the interface between the oxidizing compound and the tooth

surface due to application of the accelerator composition. The application of an accelerator composition prior to applying an oxidizing compound to the tooth enamel surface as measured in a sample of 100 cases treated recently at the Walnut Creek whitening center resulted in an average shade change of 9.3 shades as measured on the standard VITA® PAN shade scale ordered in value mode as suggested by the manufacturer. The average case achieved a whitening effect ("whitening success factor") representing 91% of the difference between the starting shade and the top of the VITA® PAN shade guide. Significantly, 96% of starting shades D3 and lighter ended at B1.

Upon reading the subject application, various alternative constructions and embodiments will become obvious to those skilled in the art. These variations are to be considered within the scope and spirit of the subject invention. The subject invention is only to be limited by the claims which follow and their equivalents.

CLAIMS

What is claimed is:

1. A method of tooth whitening, comprising:

contacting a tooth surface of a patient with a tooth whitening composition having a pH between about 6.0 and about 12.0, wherein the tooth whitening composition comprises an oxidizing compound and an accelerator; and

exposing the tooth surface to light energy.

2. The method of claim 1, wherein the oxidizing compound is selected from the group consisting of hydrogen peroxide, carbamide peroxide, alkali metal peroxides, alkali metal percarbonates, and alkali metal perborates.

3. The method of claim 1, wherein the oxidizing compound comprises at least one of a peroxyacid compound or a peroxyacid precursor.

4. The method of claim 3, wherein the peroxyacid precursor is selected from the group consisting of glyceryl triacetate, acetylated amino acids, acetylsalicylic acid, and N,N,N',N'-tetraacetyl ethylenediamine, vinyl acetate polymers and copolymers, acetylcholine, and other biologically acceptable acetylated compounds.

5. The method of claim 1, wherein the accelerator comprises an alkaline pH adjusting agent.

6. The method of claim 5, wherein the alkaline pH adjusting agent is selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, and polyethylenimine.

7. The method of claim 1, wherein the tooth whitening composition further comprises a thickener.

8. The method of claim 7, wherein the thickener is selected from the group consisting of carboxypolymethylene, polyacrylic acid polymers and copolymers, hydroxypropylcellulose, cellulose ethers, salts of poly(methyl vinyl ether-co-maleic anhydride), polyvinyl pyrrolidone, poly(vinylpyrrolidone-co-vinyl acetate), silicon dioxide, fumed silica, and stearic acid esters.

9. The method of claim 5, wherein the accelerator further comprises a buffer.

10. The method of claim 9, wherein the buffer comprises gylcine.

11. The method of claim 5, wherein the accelerator further comprises a surfactant.

12. The method of claim 11, wherein the surfactant comprises a zwitterionic surfactant.

13. The method of claim 11, wherein the surfactant comprises glycine.

14. A method of tooth whitening, comprising:

contacting a tooth surface of a patient with an accelerator composition having a pH between about 6.0 and about 12.0;

sequentially contacting the accelerator-treated tooth surface with an oxidizing composition; and

thereafter exposing the tooth surface to light energy.

15. The method of claim 14, wherein the oxidizing composition comprises an oxidizing compound.

16. The method of claim 15, wherein the oxidizing compound is selected from the group consisting of hydrogen peroxide, carbamide peroxide, alkali metal peroxides, alkali metal percarbonates, and alkali metal perborates.

17. The method of claim 15, wherein the oxidizing compound comprises at least one of a peroxyacid compound or a peroxyacid precursor.

18. The method of claim 17, wherein the peroxyacid precursor is selected from the group consisting of glyceryl triacetate, acetylated amino acids, acetylsalicylic acid, and N,N,N',N'-tetraacetyl ethylenediamine, vinyl acetate polymers and copolymers, acetylcholine, and other biologically acceptable acetylated compounds.

19. The method of claim 15, wherein the accelerator composition comprises an alkaline pH adjusting agent.

20. The method of claim 19, wherein the alkaline pH adjusting agent is selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, and polyethylenimine.

21. The method of claim 14, wherein at least one of the accelerator composition and the oxidizing composition comprise a thickener.

22. The method of claim 21, wherein the thickener is selected from the group consisting of carboxypolymethylene, polyacrylic acid polymers and copolymers, hydroxypropylcellulose, cellulose ethers, salts of poly(methyl vinyl ether-co-maleic anhydride), polyvinyl pyrrolidone, poly(vinylpyrrolidone-co-vinyl acetate), silicon dioxide, fumed silica, and stearic acid esters.

23. The method of claim 19, wherein the accelerator composition further comprises a buffer.

24. The method of claim 23, wherein the buffer comprises gylcine.

25. The method of claim 23, wherein the accelerator composition comprises potassium hydroxide and glycine.

26. The method of claim 19, wherein the accelerator composition further comprises a surfactant.

27. The method of claim 26, wherein the surfactant comprises a zwitterionic surfactant.

28. The method of claim 27, wherein the surfactant comprises glycine.

29. The method of claim 14, wherein the accelerator composition comprises a photosensitive agent.

30. The method of claim 29, wherein the photosensitive agent comprises a metal-ligand complex that absorbs light in the range of from about 350 nm to about 700 nm.

31. The method of claim 30, wherein the metal-ligand complex comprises ferrous chloride.

32. The method of claim 29, wherein the photosensitive agent comprises a chelator.

33. The method of claim 32, wherein the chelator is selected from the group consisting of ethylenediamine tetraacetic acid, diethylenetriamine pentaacetic acid, nitrilotriacetic acid, 1-hydroxyethylidene-1,1-diphosphonic acid, ethylenediamine tetra(methylenephosphonic acid), and diethylenetriamine penta(methylenephosphonic acid),.

34. The method of claim 29, wherein the photosensitive agent is selected from the group consisting of sorbitol, xylitol, mannitol, maltitol, lactitol and other non-carboxylated polyhydroxy compounds

35. The method of claim 29, wherein the photosensitive agent comprises 1-hydroxyethylidene-1,1-diphosphonic acid and ferrous chloride.

36. The method of claim 19, wherein the accelerator composition further comprises a photosensitive agent.

37. The method of claim 15, wherein the oxidizing compound is present in an amount of from about 1.0 % to about 40.0% by weight of the oxidizing composition.

38. The method of claim 15, wherein the oxidizing compound is present in an amount of from about 10.0 % to about 20.0% by weight of the oxidizing composition.

39. The method of claim 15, wherein the oxidizing compound is present in an amount of from about 20.0 % to about 30.0% by weight of the oxidizing composition.

40. The method of claim 15, wherein the oxidizing compound is present in an amount of from about 30.0 % to about 40.0% by weight of the oxidizing composition.

41. The method of claim 19, wherein the alkaline pH adjusting agent is present in an amount of from about 0.1 % to about 90.0 % by weight of the accelerator composition.

42. The method of claim 19, wherein the alkaline pH adjusting agent is present in an amount of from about 1.0 % to about 20.0 % by weight of the accelerator composition.

43. The method of claim 19, wherein the alkaline pH adjusting agent is present in an amount of from about 1.0 % to about 10.0 % by weight of the accelerator composition.

44. The method of claim 14, wherein the oxidizing composition comprises hydrogen peroxide and wherein the accelerator composition comprises potassium hydroxide, glycine, polyvinyl pyrrolidone, and water.

45. The method of claim 14, wherein the oxidizing composition comprises hydrogen peroxide and wherein the accelerator composition comprises 1-hydroxyethylidene-1,1-diphosphonic acid, ferrous chloride, and water.

46. A composition for accelerating whitening teeth, comprising:

an alkaline pH adjusting agent;

an aqueous carrier; and

at least one performance enhancing adjuvant.

47. The composition of claim 46, wherein the alkaline pH adjusting agent is selected from the group consisting of sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium carbonate, potassium carbonate, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, and polyethylenimine.

48. The composition of claim 46, wherein the at least one performance enhancing adjuvant is selected from the group consisting of a buffer, a surfactant, a thickener, a film-forming ingredient, a penetration enhancer, and a desensitizing agent.

ABSTRACT

The tooth whitening compositions of the present invention include an oxidizing compound and an accelerator. The oxidizing compound and the accelerator may be administered in the same or different composition. The present invention further relates to a method of whitening teeth includes contacting the tooth enamel surface of a patient with composition comprising an oxidizing compound and an accelerator, and, thereafter, exposing the tooth surface to light energy. Alternatively, a method of whitening teeth includes contacting the tooth enamel surface of a patient with an accelerator, then contacting the treated tooth surface with the oxidizing compound, and, thereafter, exposing the tooth surface to light energy.

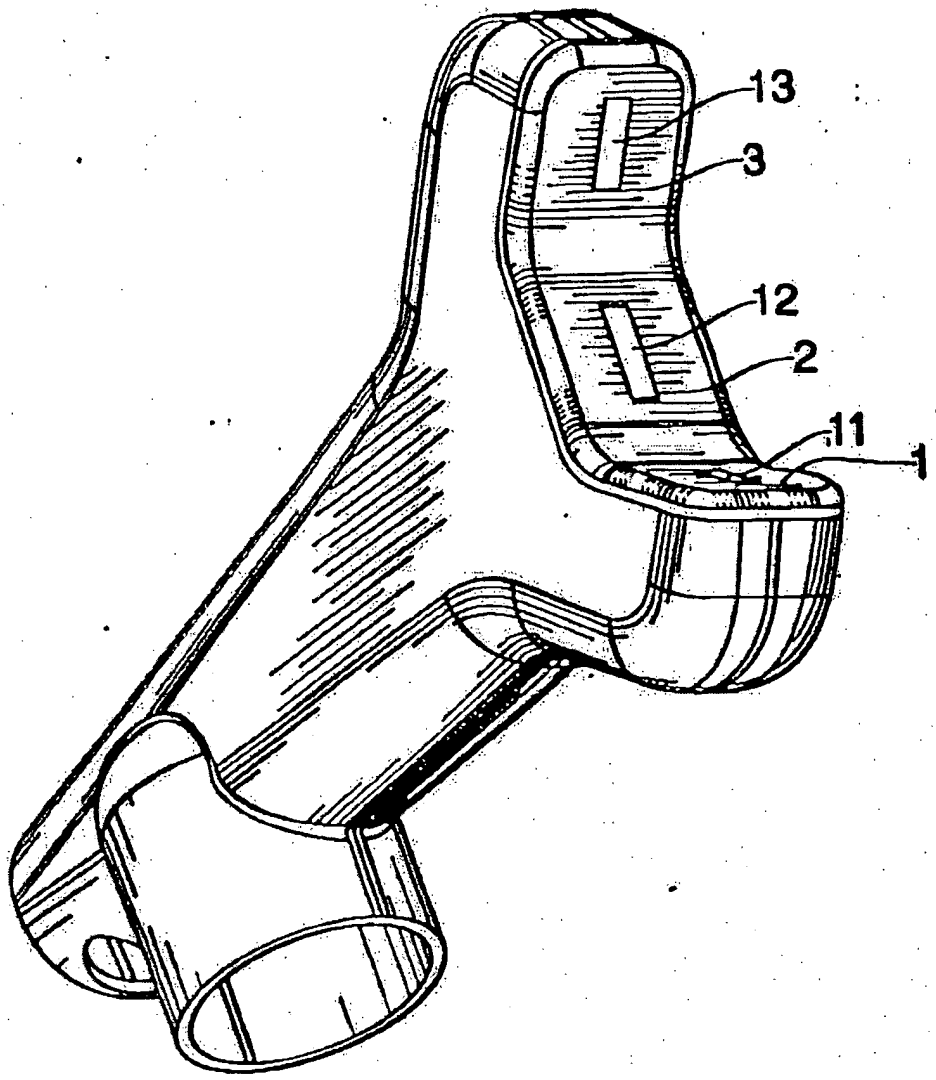

FIG. 1

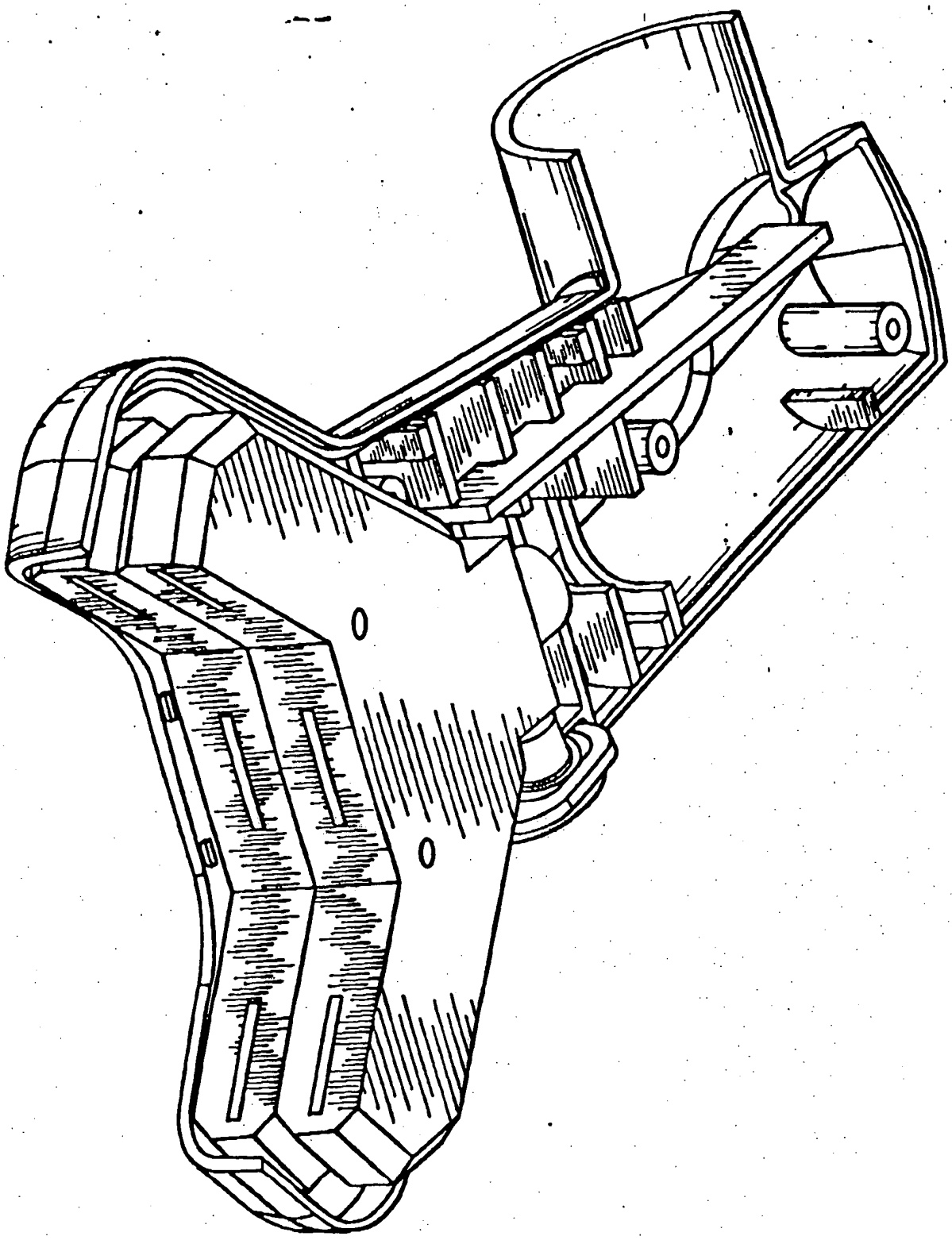

FIG. 2

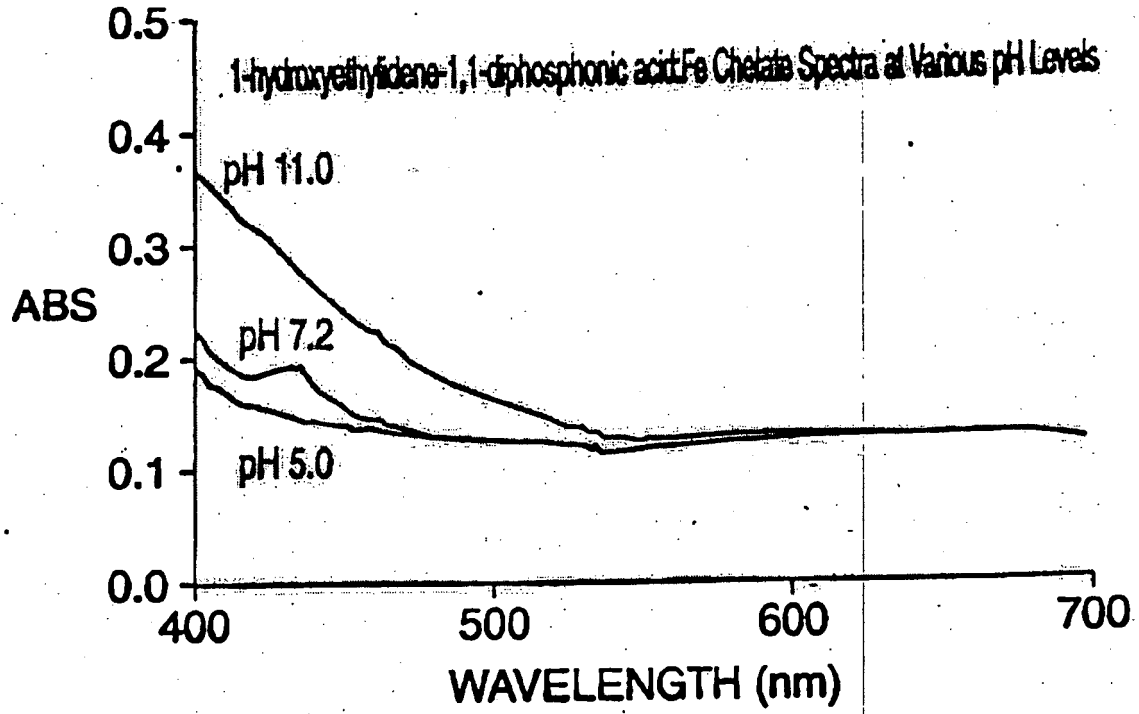

FIG. 3

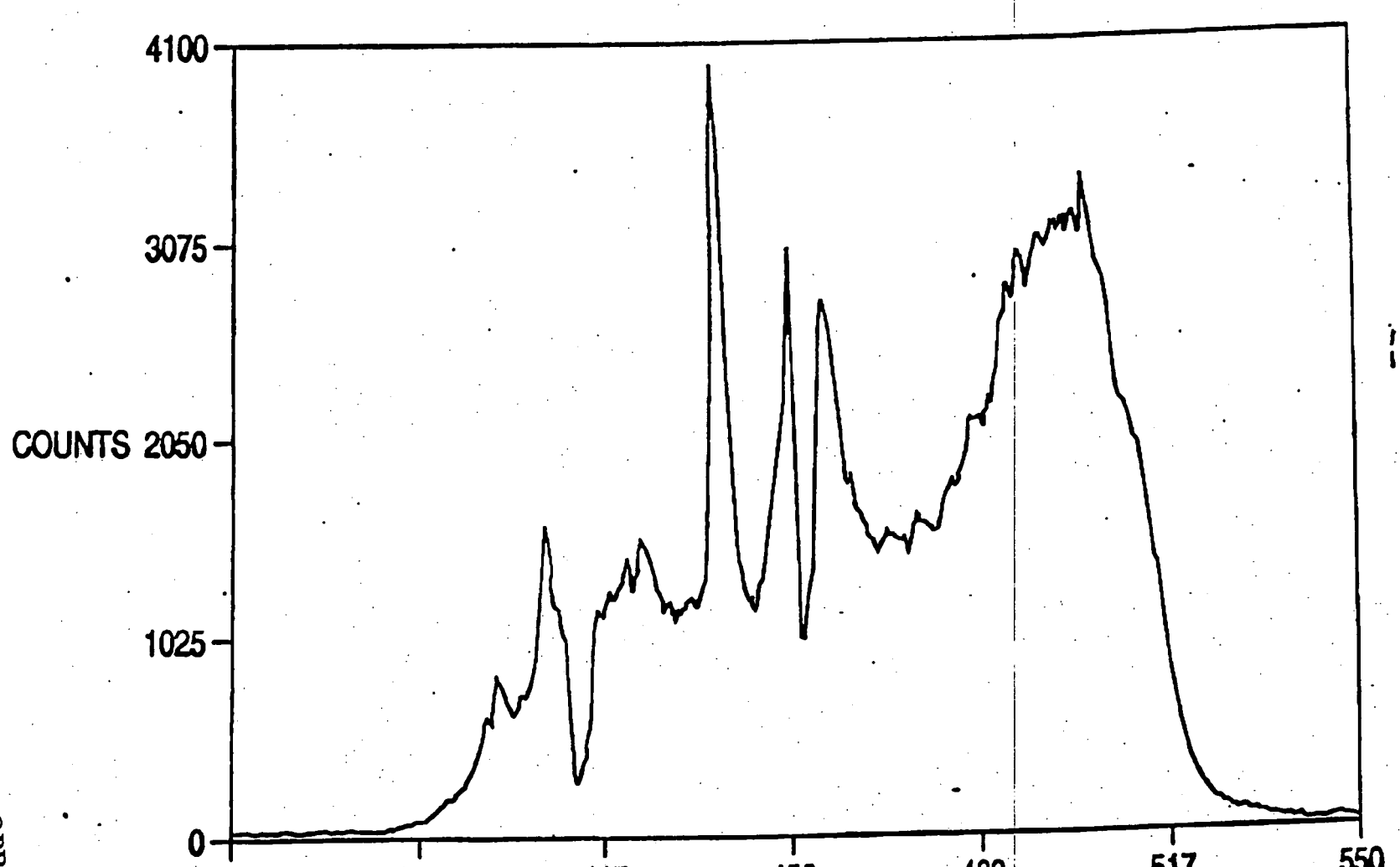

FIG. 4A

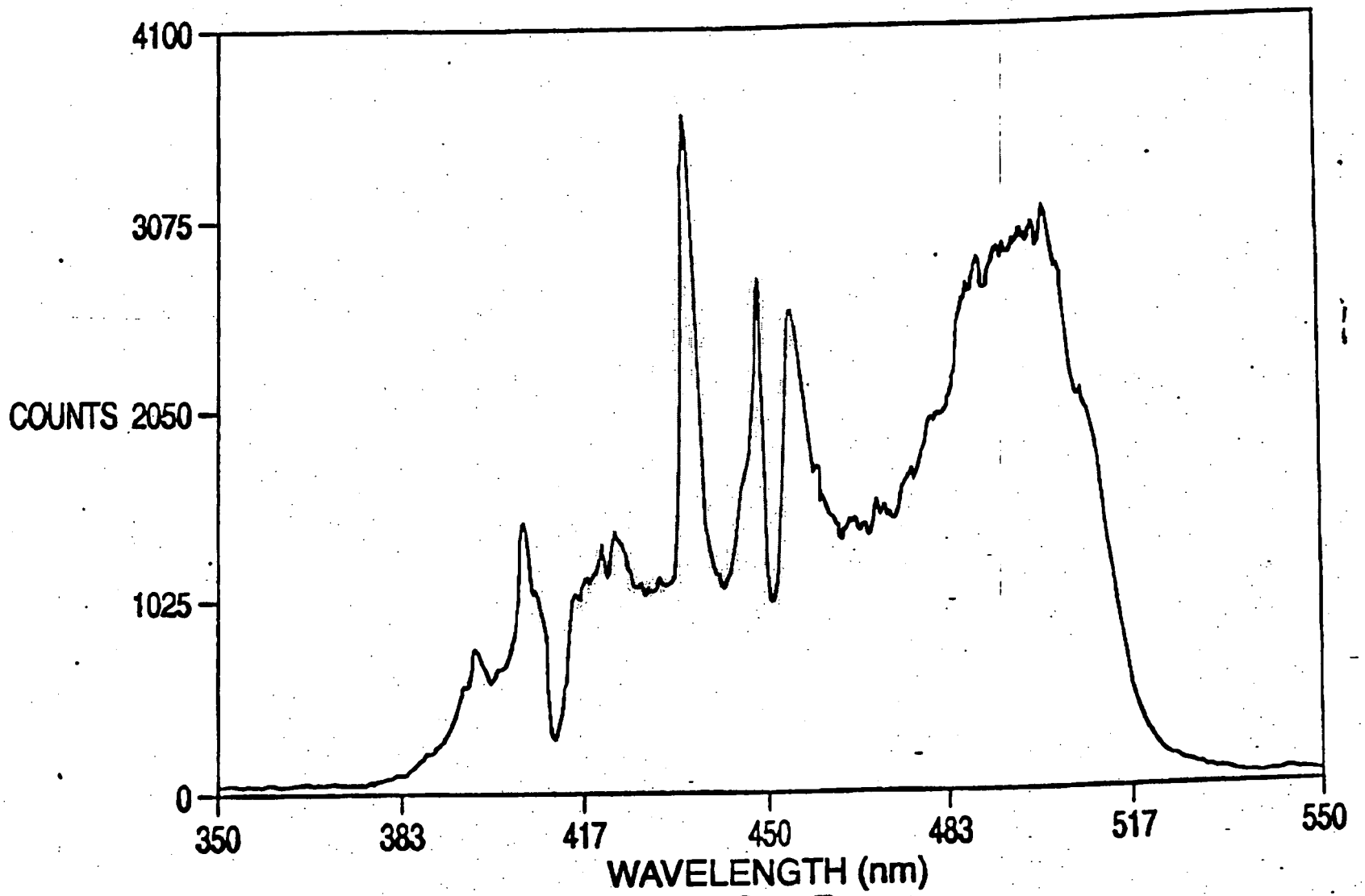

FIG. 4B

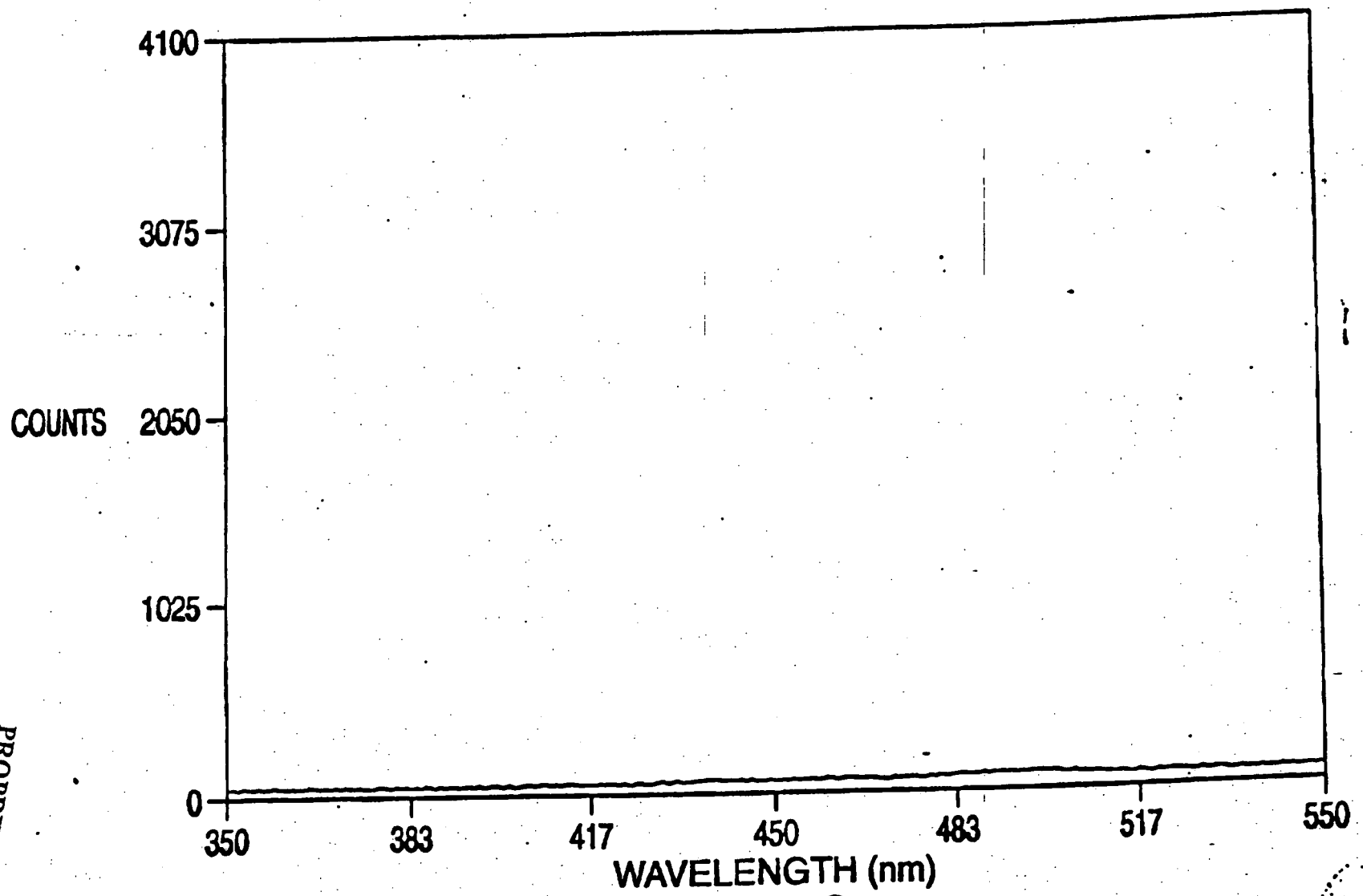

FIG. 4C

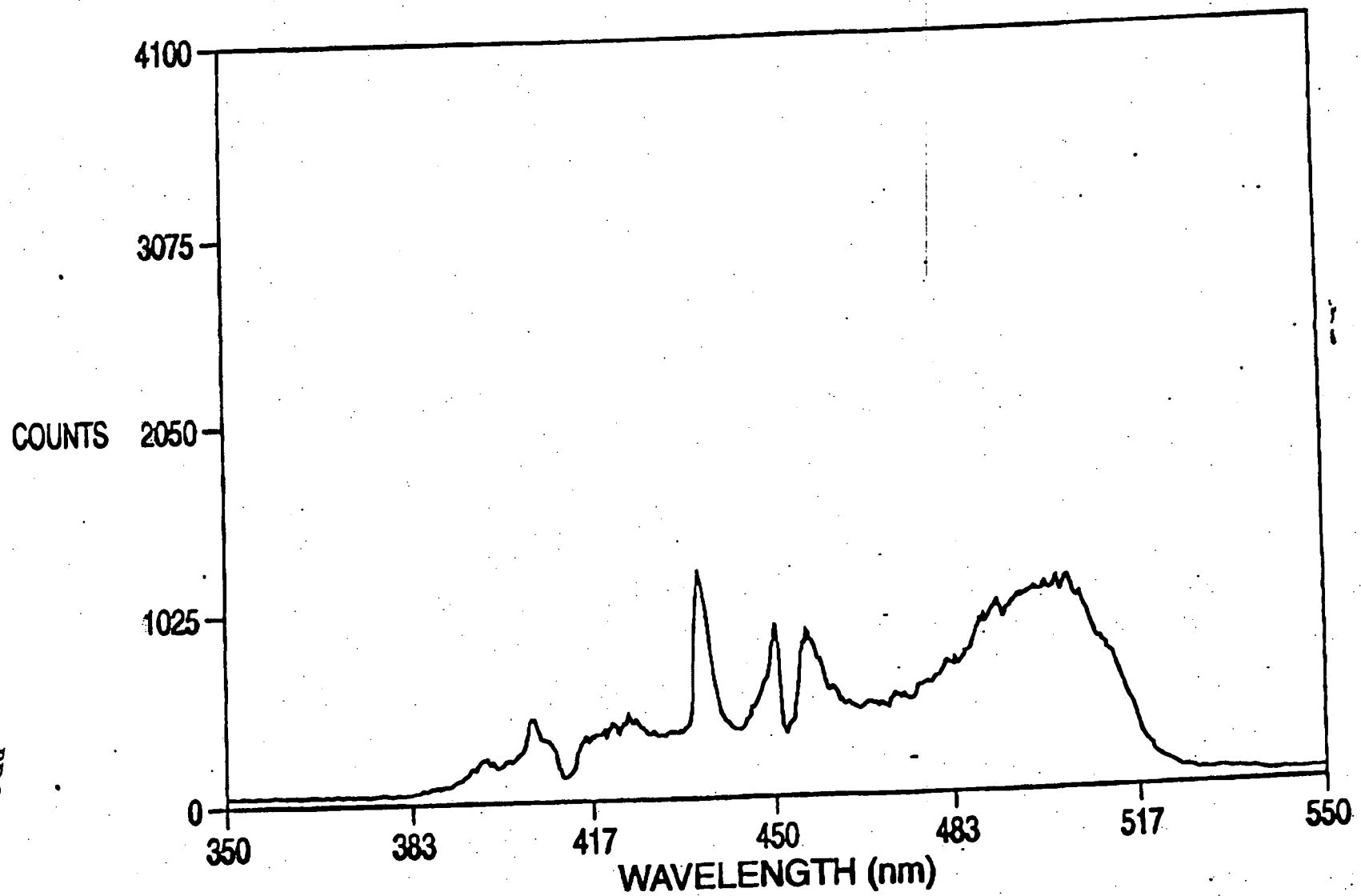

FIG. 4D

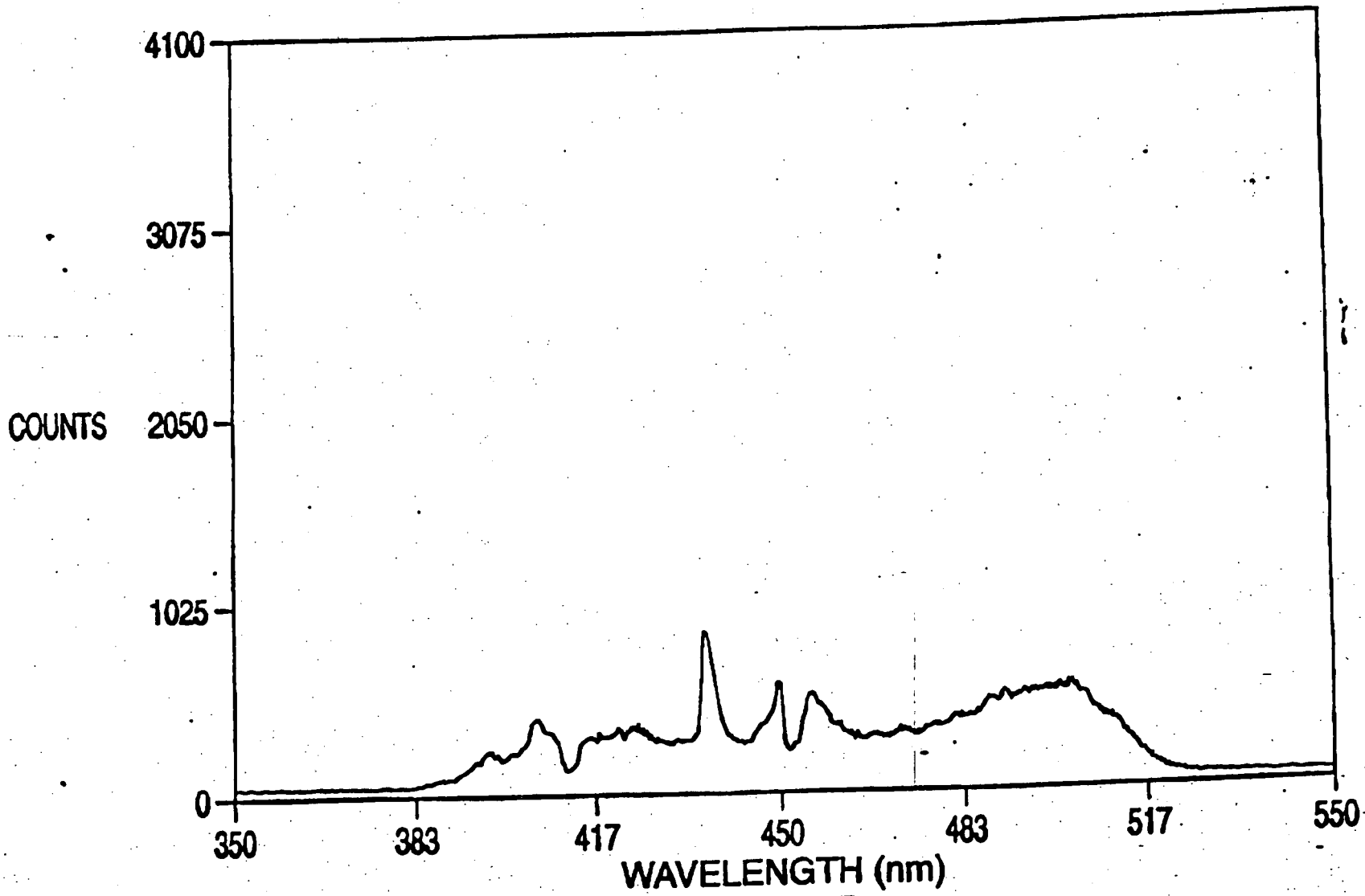

FIG. 4E

Fig. 5

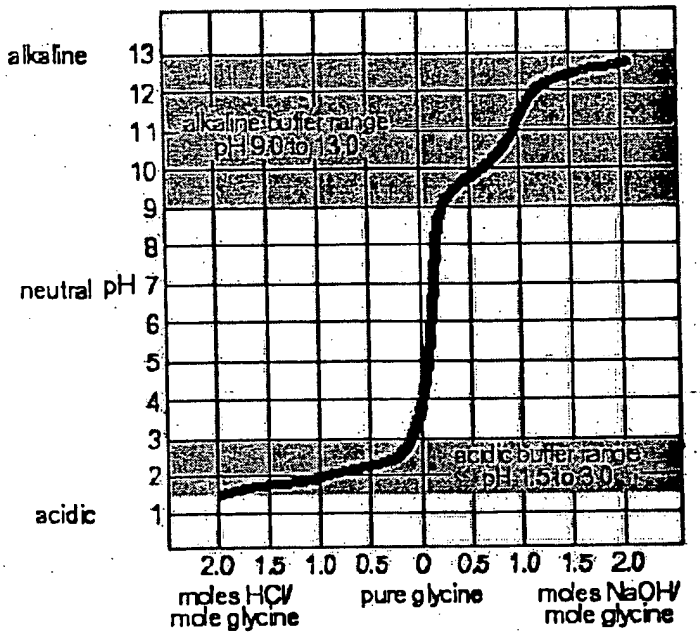

FIG. 6

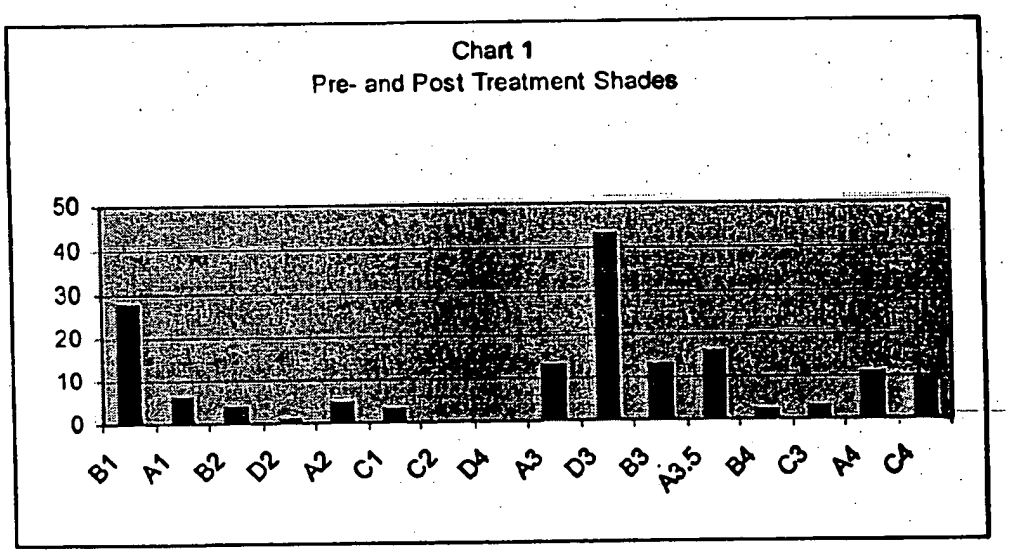

FIG. 7